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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on the Maternal Immunizations Working Group Phase II's Draft Report and Draft Recommendations for Overcoming Barriers and Identifying Opportunities for Developing Maternal Immunizations for Consideration by the National Vaccine Advisory Committee.

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

ACTION: Notice.

SUMMARY: The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act (P.L. 99-660) (§ 2105) (42 U.S. Code Section 300aa-5). Its purpose is to advise and make recommendations to the Director of the National Vaccine Program on matters related to the program's responsibilities. The Assistant Secretary for Health (ASH) has been designated by the Secretary of Health and Human Services (HHS) as the Director of the National Vaccine Program. The National Vaccine Program Office (NVPO) is located within the Office of the Assistant Secretary for Health (OASH), Office of the Secretary, U.S. Department of Health and Human Services (HHS). The NVPO provides leadership and fosters collaboration among the various federal agencies involved in vaccine and immunization activities. The NVPO also provides management and support services for the National Vaccine Advisory Committee (NVAC). The NVAC advises and makes recommendations to the ASH in his/her capacity as the Director of the National Vaccine Program on matters related to the program's responsibilities.

Recognizing the importance and impact of maternal immunizations on public health, the ASH charged the NVAC in June 2012 with reviewing the state of maternal immunizations and existing best practices to identify programmatic gaps and/or barriers to the implementation of current recommendations regarding maternal immunization. The NVAC established the Maternal Immunization Working Group (MIWG) in August 2012 to conduct these assessments and provide recommendations for overcoming any identified barriers.

Through a series of teleconferences, electronic communications, and public discussions during the NVAC meetings, the working group identified a number of draft recommendations for consideration by the NVAC. These recommendations represent opportunities for developing and licensing new vaccines for pregnant women. The draft report and draft recommendations from the working group will inform NVAC deliberations as the NVAC finalizes their recommendations for transmittal to the ASH.

On behalf of NVAC, NVPO is soliciting public comment on the draft report and draft recommendations from a variety of stakeholders, including the general public, for consideration by the NVAC as they develop their final recommendations to the ASH. It is anticipated that the draft report and draft recommendations, as revised with consideration given to public comment and stakeholder input, will be presented to the NVAC for adoption in September 2016 at the quarterly NVAC meeting.

DATES: Comments for consideration by the NVAC should be received no later than 5:00 p.m. EDT on September 9, 2016.

ADDRESSES:

1) The draft report and draft recommendations are available on the web at **http://www.hhs.gov/nvpo/nvac/index.html**
2) Electronic responses are preferred and may be addressed to: nvpo@hhs.gov

3) Written responses should be addressed to:

National Vaccine Program Office,

U.S. Department of Health and Human Services,

200 Independence Avenue, SW, Room 733G.5,

Washington, D.C. 20201

Attn: HHS Maternal Immunizations c/o Dr. Karin Bok

FOR FURTHER INFORMATION CONTACT:

Karin Bok, MS, PhD, National Vaccine Program Office, Office of the Assistant Secretary for Health, Department of Health and Human Services; telephone (202) 690-1191; fax (202) 260-1165; email Karin.Bok@hhs.gov.

SUPPLEMENTAL INFORMATION:

I. Background

Maternal immunizations have been an effective strategy to protect both the mother and the young infant against vaccine-preventable diseases. However, significant barriers remain that prevent the development and licensing of additional vaccines for use in maternal immunization strategies. Some of those barriers include ethics and policy considerations about including pregnant women in clinical research, the need for continued support of pre-clinical and clinical research on immunity, the impact and safety of immunizations during pregnancy, and educating obstetrical providers about the benefits of immunizations during pregnancy and the importance of including pregnant women in clinical research in order to provide the highest quality of healthcare.

HHS recognized the need to address these barriers and subsequently charged the NVAC with making recommendations that would address the problem. The NVAC separated the task into two sections as it was first necessary to address and understand the demand for maternal immunizations in order to then

address the challenges in developing maternal immunizations. The MIWG Phase I focused on understanding the demand for maternal immunization programs by identifying existing patient and provider barriers to maternal immunization, which addressed the first part of the charge. Then, the MIWG Phase II focused on the second part of the charge, which was to identify barriers to and opportunities for developing vaccines for pregnant women and to make recommendations to overcome these barriers. Through a series of teleconferences, electronic communications, and public discussions during the NVAC meetings, the working group identified a number of draft recommendations. These recommendations were categorized into four priority areas that represent opportunities for developing and licensing new vaccines for pregnant women. These four categories include:

Focus Area 1: Ethical Issues

Focus Area 2: Policy Issues

Focus Area 3: Pre-Clinical and Clinical Research Issues

Focus Area 4: Provider Education and Support Issues

Within each focus area the NVAC report details key recommendations to overcoming challenges in these areas. The NVAC report also provides the rationale for these recommendations and input on how the ASH might support HHS activities in these areas.

II. Request for Comment

NVPO, on behalf of the NVAC MIWG Phase II, requests input on the draft report and draft recommendations. In addition to general comments on the draft report and draft recommendations, NVPO is seeking input on efforts and/or barriers to maternal immunizations not presented in the report where HHS efforts could advance maternal immunization efforts. Please limit your comments to six (6) pages.

III. Potential Responders

HHS invites input from a broad range of stakeholders including individuals and organizations that have interests in maternal immunization efforts and the role of HHS in advancing those efforts.

Examples of potential responders include, but are not limited to, the following:

- general public;
- advocacy groups, non-profit organizations, and public interest organizations;
- academics, professional societies, and healthcare organizations;
- public health officials and immunization program managers;
- obstetrical care provider groups including all physician and non-physician providers that administer healthcare services to pregnant women, including pharmacists; and
- representatives from the private sector.

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. Written submissions should not exceed six (6) pages. Please do not send proprietary, commercial, financial, business, confidential, trade secret, or personal information.

DATE: August 16, 2016

Bruce Gellin, M.D., M.P.H.

Executive Secretary, National Vaccine Advisory Committee

Deputy Assistant Secretary for Health

Director, National Vaccine Program Office

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