

August 28, 2009

Howard K. Koh, M.D., M.P.H  
Assistant Secretary for Health  
Department of Health and Human Services  
200 Independent Avenue, SW, Rm. 701-H  
Washington DC 20201

**RE: NVAC – August 24, 2009 Meeting**

Dear Dr. Koh:

This letter summarizes the National Vaccine Advisory Committee (NVAC) meeting held on August 24, 2009, and is a formal transmittal of recommendations approved by the NVAC for your review and consideration. The agenda for this meeting is enclosed.

This meeting was an off-schedule meeting, held by teleconference, designed to gather information about the evolving H1N1 influenza situation and efforts to prepare for the fall influenza vaccination campaigns, as well as to formally present recommendations on H1N1 influenza vaccine safety monitoring and communications policy to the NVAC for approval. It was a pleasure to have you join the meeting and offer your perspectives on the situation and receive updates on the steps that have been taken by the Department of Health and Human Services (HHS) to the recommendations on H1N1 influenza vaccine safety and financing made by the NVAC in July 2009.

The initial presentations highlighted the recent efforts of the Federal response to the H1N1 influenza situation, including the development and implementation of the Federal H1N1 vaccination program. Dr. Beth Bell informed the NVAC that the recently approved Advisory Committee on Immunization Practices recommendations on H1N1 influenza vaccine prioritization were published in the Morbidity and Mortality Weekly Report, with supplemental information available on-line. Dr. Robin Robinson provided an update on the on-going vaccine clinical trials. To this point, he stated that there have been no serious adverse events reported and initial dosing data from the trials should be available by the middle of September. To ensure availability of usable vaccine following licensure, vaccine “fill and finish” processes have already begun by the manufacturers. It is anticipated that there will be delivery of 45 to 50 million vaccine doses by the middle of October, with an additional 10 to 20 million doses weekly, thereafter.

Dr. Marie McCormick presented a proposed recommendation from the NVAC Vaccine Safety Working Group H1N1 Influenza Subgroup for the NVAC to consider. The proposed

recommendation addressed two key issues: 1) the need to develop background rates of vaccine-associated adverse events in the general population, and 2) the need for HHS to conduct practice exercises on addressing vaccine safety scenarios that may occur during a mass vaccination campaign, to ensure the government is prepared for such situations. Following this presentation, NVAC members were invited to ask questions and provide comment, with a vote scheduled to follow opportunity for public comment. Dr. Daniel Salmon provided a detailed update on the HHS response to the NVAC vaccine safety recommendations approved in July 2009, including efforts to examine claims data from managed care organizations covering approximately 50 million Americans to study the incidence of possible adverse vaccination outcomes.

Communication with the public will be a very important part of the H1N1 response. Ms. Jenny Backus, Acting Assistant Secretary for Public Affairs, reviewed the communications plans under development and implementation in HHS. Her presentation focused on the varied forms of outreach planned, including the use of “new media” such as Twitter and Facebook alongside traditional media venues of radio and television advertisements. Following Ms. Backus’ presentation and related discussion, I presented a proposed recommendation for the NVAC’s consideration addressing the need for a comprehensive and detailed communications plan for the H1N1 influenza vaccination program to be developed. Following this presentation, NVAC members were invited to ask questions and provide comment, with a vote scheduled to follow opportunity for public comment.

Dr. Bruce Gellin provided a detailed assessment of the HHS efforts to respond to the NVAC H1N1 vaccine finance recommendations approved in July 2009, highlighting the difficulty in coordinating recommendations made to your office across many different parties of the Federal government. Dr. Jeff Kelman reviewed the efforts made at the Centers for Medicare and Medicaid Services (CMS) to respond to the NVAC recommendations that directly impact CMS, including the full coverage of H1N1 influenza vaccine administration by Medicare, with ongoing discussions for Medicaid.

Engagement with public health partners is a key part of the NVAC’s ongoing review of the implementation of the 2009 H1N1 influenza vaccination program. The NVAC next received briefings from State and local health partners on their planning and needs for H1N1 influenza response. Updates were provided by Ms. Anna Buchanan (Association of State and Territorial Health Officials [ASTHO]), Dr. Anne Bailowitz (National Association of County and City Health Officials), and Ms. Claire Hannan (Association of Immunization Managers). The speakers thanked the Federal government for the response to date. Concern was expressed about a number of issues: (1) the need to move along distribution of funds for H1N1 influenza vaccination planning efforts; (2) the continuing uncertainty about the availability and distribution of vaccine; (3) the need for a clearer definition of the role that local health departments will play; (4) the need for the CDC medical provider vaccine agreement form to be finalized so that recruitment of providers of vaccine can be completed, and (5) some continuing uncertainties about insurance reimbursement for H1N1 influenza vaccine administration. Ms. Buchanan informed the committee about an upcoming meeting between ASTHO and chain stores and pharmacies regarding their role in distributing vaccine.

The final update was provided by Dr. Patricia Quinlisk (Chair, National Biodefense Science Board [NBSB]), who informed the NVAC on the work of the NBSB regarding two issues: first the combining of live, attenuated influenza vaccine with inactivated influenza vaccine for the anticipated two doses that will be needed for most vaccine recipients; and second, concerns with addressing mental health issues that may arise in 2009 H1N1 influenza vaccination programs. Dr. Andy Pavia indicated that the NBSB is looking to address H1N1 influenza issues that may not be currently addressed by other advisory committees at their September meeting.

The meeting was opened for public comment, with two individuals providing comments in the teleconference. The first public comment included the need for complete transparency in the H1N1 influenza vaccine clinical trials along with a call for the removal of thimerosal from influenza vaccine. The second comment reflected views from a public engagement session on the 2009 H1N1 influenza vaccination campaign. At this particular session, views were expressed 1) on the barriers to uptake of the vaccine including the need for clear explanations as to why the vaccine is necessary, 2) the need for free vaccination to be provided in the most convenient way possible to encourage uptake, and 3) clear communication about the number and availability of vaccination clinics to the general population. Additionally, one written public comment was received prior to the meeting, from the National Association of Community Health Centers, calling for consideration of support for community health center reimbursement for vaccination of uninsured patients and the ability to transfer vaccine between locations of a singly incorporated health center under one provider agreement.

Following public comment, the vaccine safety and communications recommendations were brought to a vote. Both recommendations were approved unanimously. The full text of these sets of recommendations is enclosed with this letter.

The meeting concluded with a reminder that the upcoming in-person NVAC meeting to be held on September 15-16, 2009 will devote a large portion of the agenda to H1N1 influenza vaccination issues and status updates.

Please feel free to contact me with any questions or concerns you may have in regard to any of the Committee's activities. I would also like to invite you to attend our next NVAC meeting, which is scheduled for September 15-16, 2009. Of course, I am available at any time to speak to you by telephone or to meet in person.

Sincerely,

/ Guthrie S. Birkhead/  
Guthrie S. Birkhead, M.D., M.P.H.  
Chair, National Vaccine Advisory Committee

Enclosures