

The National Vaccine Advisory Committee (NVAC)

**Letter from the Chair to the Assistant Secretary for Health,
RE: NVAC – July 27, 2009 Meeting**

July 31, 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 – July 27, 2009 Meeting

Dear Dr. Koh:

This letter summarizes the National Vaccine Advisory Committee (NVAC) meeting held on July 27, 2009, and is a formal transmittal of the 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 financing policy to the NVAC for approval. It was a pleasure to have you join the meeting and offer your perspectives on the situation and planning efforts.

The first three presentations of the meeting provided key background information about the current state of the H1N1 influenza pandemic. RADM Anne Schuchat gave a brief update on viral transmission in both the US and the Southern Hemisphere, where in some countries it is the predominant circulating strain. This highlights the need for the surveillance, community measure, vaccination, and communication efforts currently underway or in development at the Centers for Disease Control and Prevention (CDC). Dr. Robin Robinson informed the NVAC that production of H1N1 influenza vaccine for clinical trials and commercial distribution has begun. While production yields are only about 30% of those typically seen for seasonal influenza, this was within the levels deemed acceptable for the production of such a novel vaccine. Dr. Robinson indicated that some clinical trials have already begun, and others will be starting soon, with earlier trials enrolling adults and later trials including children and pregnant women. Dr. Jay Butler briefed the Committee on the implementation planning for a vaccination program, highlighting the differences between previous planning assumptions and the current situation and presenting the new assumptions incorporated into these planning scenarios.

Dr. Marie McCormick presented three recommendations from the H1N1 influenza subgroup of the NVAC Vaccine Safety Working Group. Briefly, these recommendations call for (1) development of a clear Federal plan for monitoring the safety of the 2009 H1N1 influenza vaccine, (2) development of methods to link exposure (vaccine) information to outcome (adverse event) information, on as large of a population level as possible, and (3) formation of an independent Vaccine Safety Assessment Committee to advise both you and the Assistant Secretary for Preparedness and Response on the presence, investigation, interpretation and implications of possible side effects of H1N1 influenza vaccines. Following this presentation, NVAC members were invited to ask questions and provide comment, with a vote scheduled to follow the public comment period.

Megan Lindley presented six recommendations on financing policy for the H1N1 influenza vaccine. These recommendations are based on the principles of the Vaccine Finance Working Group recommendations approved by the NVAC in September 2008. Briefly, these recommendations fall into four categories: (1) first dollar coverage for administration of the 2009 H1N1 influenza vaccine, (2) reimbursement rates for administration of the 2009 H1N1 influenza vaccine, (3) community vaccinators and administration of the 2009 H1N1 influenza vaccine, and (4) funding to states for administration of the 2009 H1N1 influenza vaccine. Following this presentation, NVAC members were invited to ask questions and provide comment, with a vote scheduled to follow the public comment period.

The NVAC received briefings from state and local health partners on their planning and needs for H1N1 influenza response. Updates were provided by Dr. Paul Jarris (Association of State and Territorial Health Officials), Dr. Anne Bailowitz (National Association of County and City Health Officials), and Claire Hannan (Association of Immunization Managers). Concern was expressed about the methods used to track distribution of vaccine, staffing levels to address the upcoming influenza season and vaccination program communication.

The final updates were provided by representatives from three advisory committees involved in influenza preparedness – Dr. Dale Morse (Advisory Committee on Immunization Practices [ACIP]), Dr. Patricia Quinlisk (National Biodefense Science Board [NBSB]), and Dr. John Modlin (Vaccines and Related Biological Products Advisory Committee). Dr. Morse updated the Committee on upcoming ACIP activities relating to H1N1 influenza vaccine prioritization. Dr. Quinlisk provided information on recent recommendations approved by the NBSB that are being sent to the Secretary of the Department of Health and Human Services. Dr. Modlin discussed the regulatory issues surrounding the H1N1 influenza vaccine and plans for related clinical trials.

The meeting was opened for public comment, with three individuals providing comments. Public comment included the inclusion of community and faith-based organizations into vaccination program planning discussions, concern about production limitations with concomitant production of seasonal and pandemic influenza vaccines, and concern about clinical trials in infants younger than two years old and the manufacture of vaccine outside of the United States. Following public comment, the vaccine safety monitoring and vaccine financing policy

recommendations were brought to a vote. Both sets of recommendations were approved unanimously. The full text of these sets of recommendations is enclosed with this letter.

The meeting concluded with a request to identify areas to focus on for the next NVAC meeting on H1N1 influenza. Topics under consideration include communication, vaccine distribution and tracking, school-based vaccination clinics and Family Educational Rights and Privacy Act requirements, public engagement, and preparations by other governmental agencies, including the Indian Health Service and Immigration and Customs Enforcement.

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 H1N1 influenza teleconference meeting, which is scheduled for August 24, 2009. Of course, I am available at any time to speak to you by telephone or to meet in person.

Sincerely,

A handwritten signature in black ink that reads "Guthrie S. Birkhead MD". The signature is written in a cursive style with a large initial "G".

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

Enclosures