

The National Vaccine Advisory Committee (NVAC)

**Letter from the Chair to the Acting Assistant Secretary for Health,
RE: NVAC - February 5-6, 2009 Meeting**

July 9, 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 – May 7, 2009 and June 2-3, 2009 Meetings

Dear Dr. Koh:

I would like to once again welcome you as Assistant Secretary for Health (ASH). As a follow-up to my letter of June 23, 2009, this letter is a standard report of the discussion and recommendations of the National Vaccine Advisory Committee (NVAC) meetings held in May and June 2009, as well as a formal transmittal of recommendations approved by the NVAC for your review and consideration. The agendas for these meetings are enclosed.

May 7 Meeting (conference call).

Dr. Dan Salmon, National Vaccine Program Office (NVPO), gave a presentation that outlined the Vaccine Safety Working Group (VSWG) review of the Centers for Disease Control and Prevention (CDC) Immunization Safety Office (ISO) draft research agenda, focusing on the recommendations developed by the VSWG. This report was followed by discussion of the recommendations and report by NVAC members, including liaison and ex officio members, as well as members of the public. These comments were addressed, and where possible, incorporated into the final draft of the report presented to the full NVAC for voting on June 2.

June 2-3 Meeting (routinely scheduled meeting).

Report of the Chair. The first day of the meeting, June 2, began with the Report of the Chair. This report contained updates on NVAC membership and the renewal of the NVAC charter, as well as recent NVAC accomplishments. Key accomplishments noted included the finalization of the 2008 State of the Program Report, and recent activities in the area of vaccine finance, such as the publication of a Notice to Readers in the Morbidity and Mortality Weekly Report to announce the approval of the NVAC vaccine finance recommendations, and the recent introduction of Senate Bill S.1009, the Immunization Improvement Act of 2009, to improve immunization access and financing that is in part responsive to the NVAC vaccine finance recommendations.

Report of the Principal Deputy Assistant Secretary for Health. Following the Report of the Chair, NVAC next heard from Dr. Wright regarding his thoughts on the main items on the NVAC meeting agenda, including votes on vaccine safety and adult immunization recommendations, updates regarding the novel influenza A(H1N1) outbreak, the evaluation of the NVAC being conducted by RAND and the progress of updating the National Vaccine Plan.

Vaccine Safety Recommendations. Following an update of the activities of the Vaccine Safety Working Group given by Dr. Andy Pavia, the completed VSWG report and recommendations documenting their review of the CDC ISO Scientific Agenda were formally presented to the NVAC. The 32 recommendations were unanimously approved by the NVAC. A copy of this report, including these recommendations, is enclosed with this letter. Additionally, the Committee was briefed on upcoming activities of the VSWG towards meeting its second charge - providing comment on the broader vaccine safety system in the United States.

Inter-agency Working Group to address the content of the National Children's Study. Dr. Dan Salmon provided an overview of the concerns raised by the NVAC on the collection of immunization data within the National Children's Study (NCS), which led to the creation of an Inter-agency Working Group to address the content of the NCS. Detailed information on the types of data to be collected and the means by which they will be collected were presented by Dr. Ken Schorndorf, National Institutes of Health. Dr. Dan Salmon will provide periodic updates to NVAC on the work group's activities.

Adult Immunization Recommendations. Dr. Richard Clover presented the findings of the Adult Immunization Working Group, gathered from discussion with Federal agencies involved in adult immunization over the past year, along with recommendations developed by this working group. The 16 recommendations were approved by the NVAC, and a copy of this report and recommendations is enclosed with this letter. Dr. Raymond Strikas then followed up on the approval of the Adult Immunization recommendations with a preliminary discussion of the financial impact of these recommendations, linking where possible, to the vaccine finance recommendations approved in September 2008.

Novel Influenza A (H1N1) Outbreak and Response. The majority of the afternoon of June 2 was spent with the NVAC facilitating a discussion of the ongoing novel Influenza A (H1N1) outbreak, and the response thus far. This session included an examination of the developing epidemiology of this virus, the current state of influenza vaccine development as overseen by the Biomedical Advanced Research and Development Authority (BARDA), the current status of novel influenza vaccination program and prioritization development, efforts made and needs identified by state and local public health partners in anticipation of potential vaccination campaigns, and discussion of the methods to monitor the safety of the vaccine following distribution. The final portion of the session included a series of presentations by representatives from all Federal advisory committees involved in vaccine policy, including the Vaccines and Related Biological Products Advisory Committee (VRBPAC), the NVAC, the Advisory Committee on Immunization Practices (ACIP), the Defense Health Board (DHB) and the National Biodefense Science Board (NBSB). The outcome of these discussions highlighted perceived needs from all stakeholders in the event of an influenza vaccination campaign. While

not presented as formal recommendations, I would like to note a few key issues that need to be addressed in anticipation of a large-scale influenza vaccination campaign. It is essential that the planning for such a campaign be coordinated across all levels of government, with open communication between relevant Federal agencies and advisory committees as well as with state and local government. For any such campaign to succeed, recent changes in funding of state and local health departments needs to be addressed, to ensure that adequate funding and resources are available. Additionally, for a campaign that has been estimated to involve the administration of over 600 million doses of vaccine in a short time, methods for proper documentation of vaccine receipt to ensure both appropriate vaccination delivery and accurately monitor the safety of the vaccine must be developed and disseminated.

Update on Adult Influenza Vaccination monitoring. Dr. Katherine Harris, RAND Corporation, presented results of a new survey methodology to assess adult influenza vaccine uptake during the influenza season. This technique utilizes an Internet-based survey administered to individuals who have agreed to take part in online surveys, to obtain results much sooner than traditional survey methods. The results were weighted using US Census data, and provided estimates that are comparable to those obtained through the National Health Interview Survey and the Behavioral Risk Factor Surveillance Survey.

National Vaccine Plan. With the efforts to make the updated National Vaccine Plan truly a national, and not just a Federal, plan, public engagement has been a key priority of those involved in the update. Two presentations were given to summarize these activities. CAPT. Raymond Strikas explained how public comments received through the mail and e-mail were being incorporated into the development of the National Vaccine Plan. Ms. Michelle Schaur then presented on the public engagement town hall meetings held across the US for each of the five goals of the Plan.

NVAC Evaluation Summary Report. Dr. Jeanne Ringle, RAND Corporation, presented the preliminary report on the evaluation of the effectiveness of the NVAC. This report came out of a sense of frustration that the work of the Committee was not being fully realized or implemented. A thorough examination of recent NVAC recommendations and their follow-up was conducted, along with a series of interviews of key informants in the scope of the NVAC. A series of recommendations to improve the effectiveness of the NVAC was presented, with the final presentation of the report expected by the end of July 2009. Once the NVAC has received this report, the report will be shared with your office, and I hope to be able to meet with you to discuss the report recommendations so they can be properly implemented to strengthen the working relationship between your office and the NVAC.

Vaccine Financing: Insurance Premiums for Routine Immunizations. Responsive to Recommendation #16 of the NVAC Vaccine Financing Recommendations approved in September 2008, Rose Chu, Assistant Secretary for Planning and Evaluation, Office of Health Policy, presented the results of a series of calculations performed to determine the average increases in insurance premiums if health plans were to fully cover all ACIP recommended vaccines. She is currently preparing a report which summarizes this information.

American Recovery and Reinvestment Act: Vaccines. The final presentation of the meeting highlighted the intersection between the work of the NVAC Vaccine Financing Working Group and Federal law with a review of funding for the Section 317 Immunization Grant Program included in the American Recovery and Reinvestment Act of 2009 (ARRA). Three vaccine finance recommendations addressed the 317 Program, and each of these was reflected in varying degrees by the efforts to include 317 funds in ARRA.

After a final request for public discussion and comment, the meeting was adjourned.

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 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