*University of Iowa Hospitals and Clinics*
*Office of the Chief-of-Staff*
*C512 GH*
*200 Hawkins Drive*
*Iowa City, Iowa 52242-1009*
*319-356-7735* ***Tel***
*319-353-7043* ***Fax***

January 6, 2006

John Agwunobi, M.D., M.P.H., M.B.A.
Assistant Secretary for Health
Director, National Vaccine Program
Department of Health and Human Services
200 Independence Avenue, SW, Rm. 716G
Washington, DC 20201

**RE: NVAC – November 29-30, 2005 meeting**

Dear Dr. Agwunobi:

Let me first take this opportunity, on behalf of the National Vaccine Advisory Committee (NVAC), to congratulate you on your new position at the Department of Health and Human Services (HHS). In your position as the Director of the National Vaccine Program, I am certain you will have certain issues you would like brought to the table. Last year's influenza vaccine shortage, our nation's current efforts to prepare for a potential influenza pandemic, and difficulties experienced in delivery of this year's influenza vaccine have helped bring much of NVAC's recent work to the attention of the public and policymakers. I look forward to meeting with you to discuss the direction you would like to see the Committee take under your leadership.

From presentations and discussions at the November meeting, two other worrisome issues have come to the fore. These are referred to in our usual meeting summary below, but, out of concern and for emphasis, we bring them to your attention here: 1) the impending financial crisis facing many state childhood immunization programs resulting from currently low levels of federal funding for ACIP-recommended childhood vaccines, thus creating a two-class system; and 2) the risk to successful management of the nation's seasonal influenza vaccine program inherent in a growing number of states developing and passing legislation banning thimerosal. The Committee is quite concerned that these laws could inadvertently become a barrier to access of influenza vaccine While the Committee recognizes that there is limited federal jurisdiction in this arena, we, wanted to be sure that the Department was advised of this dangerous trend.

The Committee heard several presentations on the first day of the meeting relating to the current influenza vaccination program. Dr. Jeanne Santoli (CDC) spoke on issues related to difficulties encountered with the influenza vaccine supply this year. The Committee recognized and reinforced the importance of improving the seasonal demand for influenza vaccine and voiced support to consider ways that influenza vaccine campaigns could be extended and be continued into January and February 2006, in order to use all available supplies, especially to immunize individuals in areas where vaccine supplies may have lagged behind.

As noted above, vaccine financing is emerging as one of the critical issues for our Nation. Dr. Lance Rodewald (CDC) reviewed the difficult financial issues arising as ACIP recommends approval of new vaccines for children and states search for resources to finance new and old vaccines within their current federal funding limits.. NVAC will further study this important issue, seeking approaches that will help identify options or solutions.

Dr. Rajeev Venkayya (White House Homeland Security Council) presented an overview of the President's National Strategy for pandemic influenza. Then Dr. Linda Lambert (NIH) reviewed ongoing NIH-supported H5N1 vaccine clinical trials. These trials have focused on vaccine immunogenicity, efficacy, dose-sparing strategies, and adjuvants. HHS is also supporting pandemic influenza vaccine development and Dr. Robin Robinson (HHS) outlined the agency's work with domestic and international partners to secure the supplies necessary to produce pandemic vaccine domestically and encourage the use of novel technologies for vaccine production.

On the second day of the meeting, the committee heard updates from the following agencies: NIP/ACIP (Dr. Larry Pickering, ACIP), ACCV/VICP (Dr. Geoff Evans, HRSA), VRBPAC/FDA (Dr. Ruth Karron, FDA/CBER), NIH (Dr. George Curlin, NIH), CMS (Dr. Randolph Farris, CMS), DOD (Dr. John Grabenstein), USAID (Dr. Murray Trostle), and the VA (Dr. Lawrence Deyton, VA). These updates were followed by a brief review of the 2005 AHIP Immunization Survey, intended to assess the immunization practices and policies of its member health insurance plans, presented by Dr. Steve Black. A final summary report in expected in the coming months.

The four NVAC subcommittees presented summaries of their meetings the previous afternoon. The Subcommittee on Vaccine Development and Supply discussed the pediatric vaccine stockpile, state thimerosal legislation, and the work of the Regulatory Harmonization Workgroup. The subcommittee recommended that NVAC seek to identify mechanisms that would allow access to vaccines not currently licensed in the United States, but in use in other countries in cases of outbreak (specifically, polio and pandemic influenza). The Workgroup is concerned that the current IND mechanism lacks the flexibility needed to respond to such an emergency. Dr. Melinda Wharton (CDC) presented a report on current and proposed state-based thimerosal legislation to the subcommittee and subsequently to the full Committee. The implications of her report were important and of concern, as stated at the outset of this letter. At a minimum, the Committee felt that states passing such legislation should be certain to include exemptions to ensure that such legislation does not hinder distribution of influenza vaccine during either a severe influenza vaccine shortage or a pandemic.

The Subcommittee on Immunization Coverage reported that they will present a draft White Paper on Adolescent Vaccination, covering such topics as venues of care, financing, ensuring supply, and communications strategies, to the full committee within the next year. The Subcommittee on Vaccine Safety received a summary of the HHS Interagency Vaccine Safety Group's activities and two presentations on vaccine safety pharmacogenetics. This subcommittee proposed that NVAC sponsor a vaccine safety symposium to review the policy issues associated with pharmacogenetic studies and the available data. The Subcommittee on Communication and Public Engagement meeting was devoted to developing concrete goals for the subcommittee and discussing topics for future Institute of Medicine Roundtables. Such roundtables would provide, through an inclusive public process involving both topic experts and citizens with diverse backgrounds and perspectives, the opportunity for vaccine policy to be formulated with the consideration of personal values as well as science.

The committee heard four additional presentations on day two. The first, from FDA/CBER's Dr. Jesse Goodman, described the FDA Rapid Response Team's role in pandemic vaccine preparedness. Dr. Goodman's presentation highlighted for the Committee the Center for Biologics Evaluation and Research's efforts in support of pandemic preparedness: increasing manufacturing diversity and capacity; developing needed pathways and regulatory processes to speed vaccine availability; facilitating vaccine manufacturing; assuring safety and public confidence; and considering alternate pathways to prevent a pandemic. In light of Dr. Goodman's presentation, as well as that made by Dr. Lambert, of NIH, on the previous day, the Committee would like to convey to you the importance of an HHS-wide commitment to generating and sharing the data necessary to make a pandemic flu vaccine available in advance of a pandemic. It would also be beneficial to the Committee if the NIH were to share its pandemic vaccine plans and goals with the Committee.

Dr. Ben Schwartz (NVPO) presented an overview of the National Vaccine Program Office's (NVPO) Unmet Needs program; he reviewed current projects, the status of applications for next year, and preliminary results from a program outcomes assessment. In order to assess this program's potential role in addressing the unmet information needs of NVAC, subcommittee chairs will identify unmet information needs and forward them to the NVPO offices for consideration. Sarah Landry (NVPO) then delivered a report on public engagement in the pandemic influenza planning process. This process has been a critical step in determining existing public understanding of pandemic influenza in support of the development of an appropriate communication strategy, which will result in a well informed public capable of properly responding to a pandemic influenza outbreak. The final presentation came from Dr. Matthew Davis of the University of Michigan. Dr. Davis reviewed the status of insurance coverage for adult vaccines in the United States, highlighting the plight of the underinsured. The Committee is exploring the possibility of organizing a meeting that brings employers, benefits managers, labor leaders, and insurance companies together to spark a dialogue about vaccine coverage benefits.

Feel free to contact me with any questions or concerns you may have in regard to any of the Committees activities. The next NVAC meeting is scheduled for February 7-8, 2005. We hope you will be able to join us.

Sincerely yours,

Charles M. Helms

CHARLES M. HELMS, M.D., Ph.D.
*Chairman, National Vaccine Advisory Committee*

*Professor of Medicine*
*Roy J. and Lucille A. Carver College of Medicine*
*University of Iowa*

*Chief of Staff*
*University of Iowa Hospital and Clinics*

CH/ee

cc: Bruce Gellin, M.D., M.P.H.
NVAC members