DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

National Vaccine Program Office
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RE: NVAC – June 6-7, 2006 meeting

Dear Dr. Agwunobi:

I would like to thank you for assisting me in making a smooth transition into the role as Chair of the Committee. I greatly appreciate that time you have taken out of your schedule to meet with myself and Dr. Gellin to help shape the Committee's agenda. I would particularly like to thank you for your participation during our last meeting. I know the new members, Dr. Jon Almquist, Dr. Gus Birkhead, and Ms. Trish Parnell, as well as outgoing Chair Dr. Charles Helms, were very appreciative of your kind words of welcome and thanks, respectively.

We had a very full agenda at our last meeting, starting with a presentation by Dr. Lauri Markowitz, from the Centers for Disease Control and Prevention (CDC), who spoke on human papillomavirus (HPV) vaccines, addressed the connection between HPV infection and cervical cancer, the prevalence of infection, and disease burden. Two HPV vaccines are in development; one, Merck's quadrivalent vaccine (Gardasil®), as you know, was approved by the FDA on June 8 and recommended by the Advisory Committee on Immunization Practices on June 29.

The Committee then heard presentations from the Adolescent Immunization Working Group, for which I currently serve as Chair. Dr. Mary McCauley (CDC) spoke about the National Health Interview Survey. Dr. Suchita Lorick (CDC) presented information about Menactra uptake patterns among adolescents. Dr. Cynthia M. Rand (University of Rochester) addressed adolescent healthcare utilization in the United States and highlighted the fact that the majority of adolescents do not receive preventive care. Dr. Daniel B. Fishbein (CDC) spoke about school-based immunization campaigns. Lastly, I outlined the next steps for this working group, which include providing a framework for public discussion of the problems and imperatives for adolescent immunization and further discussion of the major "hot button" issues. A draft of the problem statedment regarding adolescent immunization should be available within 4 months.

Dr. Benjamin Schwartz, of the National Vaccine Program Office (NVPO), described the Unmet Needs Program and asked for NVAC input on possible program modifications to

better support NVAC and NVPO needs and priorities. The Committee discussed the creation of a task force composed of NVAC members, agency representatives, and NVPO staff to address the process of grant application review. A task-force is currently being organized by the NVPO.

Prior to adjourning for our subcommittee meetings, Dr. Joel F. Bradley (Vanderbilt University) closed the public portion of the meeting with an update on current procedural terminology (CPT) coding and reimbursement for vaccines.

The second day opened with updates from the following agencies: U. S. Agency for International Development (USAID)—Ms. Ellyn Ogden and Dr. Neal Brandes, Advisory Committee on Immunization Practices/National Center for Immunization & Respiratory Diseases (formerly the National Immunization Program) (ACIP/NCIRD)—Dr. Anne Schuchat, Advisory Commission on Childhood Vaccines/Vaccine Injury Compensation Program (ACCV/VICP)—Dr. Geoffrey Evans, Vaccines and Related Biological Products Advisory Committee (VRBPAC)/FDA—Dr. Norman W. Baylor; National Institutes of Health (NIH)—Dr. George Curlin, Centers for Medicare and Medicaid Services (CMS)—Dr. J. Randolph Farris, and Veterans Affairs (VA)—Dr. Lawrence R. Deyton.

The four subcommittees presented summaries of their meetings. Dr. Cornelia Dekker and Dr. Jerome O. Klein reported on the meeting of the Subcommittee on Vaccine Development and Supply. Dr. Dekker presented an overview of presentations made to the subcommittee by Dr. Charles J. Hackett (NIH) on the science and practicalities of vaccine adjuvants and by Dr. Elizabeth M. Sutkowski (FDA) on regulatory considerations in safety assessment of adjuvanted vaccines. Dr. Klein, addressing the issue of vaccine supply, noted that it would be unwise for recommendations for vaccine coverage to get too far ahead of the available vaccine.

Dr. Alan R. Hinman, reporting on the meeting of the Subcommittee on Immunization Coverage, addressed financial considerations relating to the rising costs and numbers of vaccines. The subcommittee proposed that efforts be made to ascertain the current prevalence and likely projection of underinsured citizens in the United States and that employers, providers, and other stakeholders should be asked for input as to how the increasing costs can be managed.

Dr. Sharon G. Humiston, in her summary of the meeting of the Subcommittee on Communication and Public Engagement, presented a report on a CDC-funded study on the design of health education materials for adolescents and their parents. The information-seeking behaviors of adolescents, parents, and healthcare personnel were analyzed to the end of targeting the information most effectively.

Dr. Andrew Pavia gave the report of the Subcommittee on Safety. The discussion centered on the formation of a new working group to implement the Institute of Medicine's recommendation that NVAC review the Vaccine Safety Datalink research agenda. The Vaccine Safety Research Working Group is currently being formed and it is anticipated the Working Group will host a "town hall" style meeting in an effort to obtain public input on the CDC's Immunization Safety Office research agenda.

Following the subcommittee reports, Dr. Jeanne M. Santoli (CDC) offered an update on influenza vaccination for the upcoming flu season, and Dr. Glen Nowak (CDC) spoke about the CDC's health communication efforts in regard to increasing influenza vaccination rates.

Dr. Greg Wallace (CDC) then gave an update on Menactra supply. He reviewed the introduction of the vaccine in 2005 and the initial recommendations, addressed issues

of supply and demand, and spoke of the lessons learned in the past year. Dr. Wallace reported that the CDC now recommends deferring the vaccination of 11 and 12 year olds due to limited supply of the vaccine.

Dr. Larry J. Anderson (CDC) discussed the recent mumps outbreak in the Midwest. He provided a review of the clinical and epidemiological features of the disease, discussed the history of the vaccination program from 1967 to 2005, and outlined the response of the CDC to the 2006 outbreak.

Dr. Robin Robinson (Office of Public Health Emergency Preparedness) closed the meeting with a report on pandemic influenza vaccine projects. He noted that the United States is on target to meet pandemic vaccine goals, addressed the issue of H5N1 vaccine stockpiles, and spoke of new contracts for vaccine production.

Please feel free to contact me with any questions or concerns you may have in regard to any of the Committee's activities. The next NVAC meeting is scheduled for September 26 - 27, 2006. I hope you will be able to join us.

Sincerely yours,

Gary L. Freed, MD, MPH
Chair, National Vaccine Advisory Committee