



Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

August 11, 2008

Joxel Garcia, M.D., M.B.A.
Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue, SW, Rm. 727-H
Washington, DC 20201

RE: NVAC – June 3-4, 2008 meeting

Dear Dr. Garcia:

Let me first congratulate you on your new position as Assistant Secretary for Health (ASH) at the U.S. Department of Health and Human Services. Your predecessors have been very supportive of the National Vaccine Program Office (NVPO) and the National Vaccine Advisory Committee (NVAC), and I look forward to continuing the strong relationship that has been built in the past with your office. The June NVAC meeting was my first as chair, although having been a member of NVAC for the past two years, I am very cognizant of the vital role and responsibilities of the members of this important and highly visible advisory committee. This letter summarizes our June meeting.

Since this was my first meeting as chair, I began the meeting with a presentation of the statutory basis for the National Vaccine Program, of which the ASH is the Director, spelled out in Title XXI of the Public Health Services Act. In particular, section 2105 includes the charge to NVAC to 1) recommend ways to encourage the adequate supply of safe and effective vaccines, 2) establish research priorities and other measures to enhance the safety and efficacy of vaccines, 3) assist NVPO on the implementation of sections 2102, and 2103, and 4) identify annually for NVPO the most important areas of government and non-government cooperation in implementing sections 2102, and 2103. A good discussion by NVAC members ensued and I believe that the Committee is prepared to step up to meet its charge. In particular, NVAC will be taking a hard look at its responsibility to ensure that the National Vaccine Program performs as directed in statute.

The next item on the agenda was a discussion of the report and proposed recommendations for adolescent vaccination. Dr Gary Freed led this effort as chair of the Adolescent Immunization Work Group. A number of new vaccinations have been recommended for adolescents in the past several years providing both the promise of disease prevention as well as the challenges of implementation for the public health and medical care systems. The report makes recommendations on how these challenges

should be met. The key content and policy areas in support of adolescent vaccination that were addressed in the report are the following: venue/health care utilization, content, communication/public engagement, financing, surveillance, and school mandates. I am happy to report that all 31 recommendations were unanimously approved by NVAC, with the exception of several financing recommendations, which will be considered as part of the larger Vaccine Finance Work Group recommendations to be voted on at the September 2008 NVAC meeting. The Adolescent Work Group has developed three manuscripts, two of which will be published in American Journal of Preventive Medicine in August 2008. The third manuscript is still being reviewed. A summary of the approved recommendations is attached for your review.

The next agenda item was a presentation of the draft recommendations of the Vaccine Finance Working Group. This working group has been meeting for the past year and a half to develop recommendations that address the challenges of financing the new and more expensive vaccines that have been recommended for use in the U.S. in the past several years. Dr. Walter Orenstein (Emory University and consultant to the Working Group) provided the update. A national stakeholders meeting to address these recommendations was held on April 19th and 20th. Forty-seven groups were represented at that meeting. The stakeholders ranked the 27 recommendations which Dr Orenstein discussed in detail. Because some recommendations offer conflicting actions, not all will be part of the final recommendations. There followed a discussion by NVAC which helped to clarify the areas where NVAC wants to focus in developing the final recommendations. The recommendations will be reviewed and commented on further by the committee members. A final vote on the recommendations is planned for the September NVAC meeting.

The next presentation was on the newly constituted NVAC Vaccine Safety Work Group. Dr. Andy Pavia, the Working Group chair, provided the first status report to NVAC. The charge of the work group is twofold. The first task is to undertake a review of the draft CDC Immunization Safety Office (ISO) 5 year research agenda on behalf of NVAC. Specifically, NVAC will provide advice on the content of the draft, prioritize research topics, and identify possible scientific barriers to implementing the research agenda as well as suggestions for addressing them. The second task is to review the current federal vaccine safety system and develop a white paper describing the infrastructure needs. The work group held its first meeting on April 11th. Four sub-work groups have been developed to address the research areas within the ISO research agenda. At the September NVAC meeting, the full NVAC will review the priorities and recommendations of the Vaccine Safety Work Group.

The Committee next heard from Dr. Donald Wright regarding the new HHS initiative on improving influenza immunization coverage of healthcare workers. He addressed the historic data on the generally low influenza vaccine coverage among healthcare workers and then discussed the details of the initiative. The goal of this effort is to achieve the Healthy People 2010 goal of 60% vaccination rate for health care workers.

The second day of the meeting, opened with reports from representatives of various agencies and departments as follows:

- Dr. Anne Schuchat, CDC/NCIRD
- Dr. Geoffrey Evans, VICP/HRSA
- Dr. Norman Baylor, CBER/FDA
- Dr. Bruce G. Gellin, NVPO
- Mr. George Curlin, NIAID/NIH
- COL Renata Engler, DoD

These reports were followed by a progress report from CDR Angela Shen of the NVPO on the 5 issues identified at the vaccine supply stakeholder's meeting in February. This report was requested at the previous NVAC meeting. The issues identified at the stakeholder's meeting are as follows:

- Need to provide incentives in order to maintain current vaccine manufacturers and encourage new players in the market
- Need to streamline the regulatory authority to ensure reliable production of safe and effective vaccines
- Need to strengthen liability protections for consumers, manufacturers, and providers
- Need to implement more comprehensive programs for vaccine stockpiles
- Need to develop education programs which provide information to parents and consumers about usage and value of vaccines

The second part of this update involved an industry panel made up of vaccine manufacturers. Each provided their perspective on issues/recommendations regarding vaccine supply. Represented on the panel were: Gregg Sylvester of Merck who stressed collaboration and communication; Marguerite Baxter of Novartis whose focus was the public health environment, strengthening public-private partnerships, and stockpiling of life-saving vaccines; Phil Hosbach representing Sanofi Pasteur discussed the multiple reasons for supply problems; and finally, Peter Paradiso of Wyeth addressed the importance of redundancy in the production process.

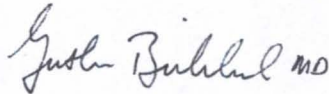
CDC officials provided a brief overview of the polio eradication program which is a high priority for CDC. They addressed the current status of the eradication program by summarizing the issues and challenges in reducing the number of countries with active cases. The new target dates are the end of 2008 for eradicating type 1 poliovirus (the most common type) and type 3 by 2009. There must be a 3 year period of abstinence of any polio cases in all WHO regions before WHO will issue a certification of eradication. Therefore, the earliest this could occur for type 1 polio would be 2012. CDC then provided an update to the report on the phase 1, pre-eradication inventory survey of laboratory containment of wild polio viral isolates submitted to the Pan American Health Organization (PAHO) in 2004. PAHO directed the survey of all biomedical facilities that retain potentially infectious wild polio virus materials in their laboratories. The original report revealed that 122 US laboratories had retained wild poliovirus material. This past April, PAHO asked for an update. Six new laboratories were identified. CDC maintains a listing of all these laboratories in their database. A phase 2 survey will be conducted one year after the last case of wild polio has been documented. Credit was given to NVAC for playing an instrumental role in the success of the original survey through sponsorship and technical guidance.

The final presenter for the June NVAC meeting was Dr Bruce Gellin, NVPO Director. He provided an update on the status of the National Vaccine Plan (NVP). The primary emphasis of the discussion was the role of the Institute of Medicine (IOM) and upcoming IOM meetings to address the NVP. An upcoming meeting on July 24th will focus on childhood, adolescent and adult programs as well as vaccine surveillance for disease and vaccine coverage. Subsequent meetings are scheduled for December 1st, February 2 and one later meeting date yet to be determined. IOM is also engaging other expert stakeholders through its expert committee. NVPO is sponsoring a 'Deliberation Day' (town hall) meeting in September to address public engagement. Three similar meetings will follow to be completed in early 2009.

After a final request for discussion and public 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. The next NVAC meeting is scheduled for September 16-17, 2008. I would like to extend an open invitation for you to attend the meeting. In addition, if you schedule permits, I would be glad to meet with you the afternoon before the meeting to review the agenda and to discuss your expectations for the Committee. Again, please accept my congratulations and best wishes.

Sincerely yours,

A handwritten signature in cursive script that reads "Guthrie Birkhead MD".

Guthrie S. Birkhead, MD, MPH
Chair, National Vaccine Advisory Committee

Enclosure

Adolescent Vaccination: Recommendations from the National Vaccine Advisory Committee – Adolescent Working Group

During the June 2008 NVAC meeting, the chair of the Adolescent Working Group presented recommendations for adolescent vaccination. The recommendations were developed in response to a request by the Assistant Secretary for Health to assess issues related to the goal of developing a comprehensive and successful adolescent immunization program in the United States. The working group identified six key areas presenting distinct challenges to realizing this goal, which is critical to the ultimate achievement of improved health outcomes among U.S. adolescents. The key areas include: venues for vaccine administration, consent for immunizations, communication, financing, surveillance, and the potential for school mandates. Having solicited input from over 40 stakeholders, the NVAC adolescent working group developed recommendations for addressing five of these areas. Recommendations designed to address challenges associated with financing adolescent vaccines, as well as those associated with vaccines for infants and children, are being developed by a separate NVAC working group. The recommendations for adolescent vaccination are intended for health policy makers, immunization program managers, health care providers, and other stakeholders. The NVAC committee unanimously approved the recommendations. A summary of the recommendations for the 5 key areas is below.

1. Venue/Health Care Utilization

Recommendations in this section were developed for the medical home and settings complementary to the medical home. NVAC believes that the medical home is an important venue for health care delivery, including immunizations, and that efforts need to be made to promote health care access and utilization of services in this setting. However, some adolescents seek preventive care less frequently from traditional sources. Recommendations for the medical home include: promoting and strengthening delivery of vaccination services in the medical home during both preventive care and, when not contraindicated, during non-preventive care visits; and, conducting research to identify effective strategies to increase utilization of recommended preventive health care visits and other opportunities that will promote adolescents' receipt of all immunizations as recommended by the Advisory Committee on Immunization practices (ACIP). Recommendations for settings complementary to the medical home include: conducting formative research to identify the acceptability and feasibility of vaccinating adolescents in non-traditional settings, and promoting and facilitating implementation of vaccination services in complementary settings shown to be appropriate and effective.

2. Consent

The right to consent to health care by minors is currently determined by state law and varies widely. All 50 states and the District of Columbia have laws related to health care consent by minors. Because some adolescents may receive health care in situations where parental or guardian consent is not easily available, recommendations were made for this topic. The recommendations include: all health care providers and their staff who may potentially provide care to adolescents should become familiar with their states law regarding a minor's right to consent to health care; health care providers and their

staff members should ensure that current Vaccine Information Statements are provided to all persons providing legal consent for adolescents' vaccinations; and, adolescents should be fully informed regarding the benefits and any potential risks associated with vaccines they receive, regardless of the individual consent laws in each state.

3. Communication/Public Engagement

The need for health communication is pronounced in the case of the adolescent immunization program because levels of knowledge of the adolescent vaccines and the diseases against which they protect are not universally high. Recommendations include: communications should be of high quality; messages should be carefully designed for audience needs; organizations involved in adolescent immunization should learn from and collaborate with a broad spectrum of groups that have interest and expertise in immunization and/or communication to youth and their parents; communication of adolescent immunization should be informed by methodologically sound research; and, a wide range of venues and media outlets should be utilized to reach target audiences.

4. Surveillance

Surveillance is expected to be an essential tool for supporting, evaluating and improving immunization among adolescents. Recommendations included: strengthening surveillance for vaccine coverage; improving surveillance for measuring disease burden; and, monitoring for vaccine safety and vaccine associated adverse events.

5. School Mandates

While school mandates have proven to be a valuable public health tool, they have also generated concern and debate regarding their ability to balance the public's health and individual/parental rights. The NVAC adolescent working group assessed the issues related to school mandates for adolescent vaccination and provided recommendations for jurisdictions considering implementation of an adolescent vaccination mandate, including: securing the input and partnership of state and local immunization program personnel and adolescent health care providers in drafting legislation/regulation regarding mandating adolescent vaccines; using the expert input of partners to address infrastructure issues that may impact the implementation of an adolescent vaccine mandate; identify ways to incorporate new mandates as seamlessly as possible into existing vaccine legislation/regulation, and ensure that new mandates do not contradict existing legislation/regulation in areas such as reporting of coverage levels, penalties for non-compliance, and immunization information system reporting requirements; and, ensuring that adequate political and public support exists before incorporating an adolescent vaccine mandate into existing state legislation/regulation.