



December 1, 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 – September 16-17, 2008 Meeting

Dear Dr. Garcia:

This letter is to report to you on the discussion and recommendations of the National Vaccine Advisory Committee (NVAC) at its September, 2008 meeting. I want to start by thanking you for attending the meeting and addressing the Committee. I know that the Committee members appreciated the time you took to be with us and were appreciative of your remarks.

The September 2008 NVAC meeting began with the Report of the Chair that addressed two key areas. The first was an update of the activities of three NVAC working groups – Vaccine Finance, Vaccine Safety, and Adult Immunization. The second was a brief discussion of NVAC's participation in the development of the new National Vaccine Plan.

Discussion of NVAC's role. Following these updates, the Committee had an in-depth discussion about the ways in which NVAC can best meet its charge, as laid out in the Public Health Services Act, and how best to convey the priorities for a strong national vaccine and vaccination enterprise especially with the upcoming transition in the Federal administration. The development of an NVAC "State of the Program" report appears to be one efficient way to document the actions the committee has taken and its recommendations for future action. Such a report could also be presented to the new administration transition team, to represent the work of the National Vaccine Program Office (NVPO) and NVAC. Two options for the format of this report were discussed – one addressing the work of NVAC as it relates to each of the responsibilities outlined in Section 2102 of the Public Health Service Act and a second addressing key program accomplishments and how they are moving forward. Discussions as to the format and content of this report are still ongoing. In order to enhance the effectiveness of NVAC, the RAND Corporation has been tasked with conducting a complete evaluation of NVAC activities. Their report will aid in guiding the direction of NVAC to ensure its actions are productive and effective. The study will be completed by early summer 2009.

Report of the Assistance Secretary for Health. Following the report of the Chair, it was a pleasure to hear your perspectives on NVPO and NVAC. Your charges to NVAC regarding the National Vaccine Plan and vaccine safety initiatives are evidence of your office's continued support of the work of the Committee.

Adolescent Working Group Recommendations follow-up. The first major action item on the agenda was a discussion on implementing recommendations from the Adolescent Working Group (AWG) that were approved by the committee at the June 2008 meeting, led by Dr. Lance Gordon and Ms. Shannon Stokley. This is in-line with NVAC's determination to monitor the implementation of its recommendations. The adolescent recommendations, and the work of the AWG, have resulted in two publications in the American Journal of Preventive Medicine, with a third publication in progress. The AWG developed a matrix to chart CDC follow-up activities related to each recommendation, along with identifying gaps where further activities will be needed. It is hoped that this will be a model for guiding the implementation of future NVAC recommendations.

Vaccine Finance Recommendations – vote for final approval. The next agenda item was a presentation of recommendations developed by the Vaccine Finance Working Group (VFWG), given by myself and Dr. Walt Orenstein. The VFWG was a broadly constituted working group consisting of representatives from clinical practice, governmental agencies, the pharmaceutical industry, insurers and employers, consumers and others. It met over the course of 2 years, including a 2 day stakeholder's meeting in April, 2008. A draft white paper including conclusions and recommendations was published for public comment with a notice in the Federal Registry. Following the comment period, revisions were made which were again shared for a comment period with the VFWG and the parent organizations represented on the group. NVAC has been kept updated on the work of the VFWG, and there was a full presentation and discussion of the draft recommendations at the June, 2008 NVAC meeting. The September NVAC meeting agenda included a presentation in detail of the final 24 consensus recommendations of the VFWG, with time for discussion and consideration of the full NVAC. After a detailed discussion, no major issues were raised and no committee members sought to have an individual vote on any recommendation. Therefore, the full slate of recommendations were voted on, and approved unanimously. The full NVAC Vaccine Financing White Paper, conclusions and final approved recommendations are attached to this letter and are being transmitted to you for your approval, dissemination and further actions to implement the recommendations. We would like to post the final report on the NVAC website as soon as it is approved.

Following the Vaccine Finance recommendation voting, one vaccine financing recommendation that originated in the AWG was presented by Dr. Lance Gordon. This recommendation would mandate first dollar coverage for vaccinations in ERISA and federal employee health plans, and thus stood in contrast with an approved VFWG recommendation that would make first dollar coverage a voluntary industry standard. Discussion on the recommendation was motioned closed, and the measure was not brought for a vote by the full committee.

Presentations on “Vaccine Hesitancy.” Next was a series of presentations on “vaccine hesitancy” by Dr. Dan Salmon, Dr. Phil Smith, Dr. Kris Sheedy, Ms. Christy Phillips and myself. Vaccine hesitancy is a term describing the concerns of some parents about vaccination safety and efficacy based on information they have seen in the media or the internet, or heard from other parents. Anecdotally, physicians are spending increasing amounts of time discussing the importance and necessity of vaccines with parents. This is an area where clear messages from medical experts and governmental public health programs on the importance of vaccine are critical to maintaining high immunization coverage levels and the societal and individual benefits that this brings. Dr. Salmon presented the effect of non-medical exemptions on immunization rates by state and locality, providing strong evidence that areas with lesser exemption criteria not only have lower immunization rates, but higher incidence of vaccine preventable diseases. Dr. Smith presented data from the National Immunization Survey related to parental concerns about vaccine safety and efficacy. Delays relative to the recommended vaccination schedule seem to be a major issue, with many parents delaying vaccines because their child is sick at the scheduled visit, in addition to concerns about safety and efficacy. Dr. Sheedy presented information on a series of focus groups held with first-time mothers and interviews with pediatricians and family physicians. The information gained from these interviews is being used by CDC to develop appropriate vaccine safety communication materials. Ms. Phillips briefly gave insight on vaccine hesitancy from the organizational perspective of the Pediatric Infectious Disease Society. I briefly provided perspectives on vaccine issues from a state health department perspective.

A key point that was raised in the discussion was the need for support for CDC’s efforts to evaluate public perceptions and to inform the public better about vaccine safety issues. NVAC recommends that HHS increase support to CDC for these efforts. In addition, NVAC recommends that the Vaccine Safety Interagency Task Force also examine the need to address the issues of public perception and risk communication around vaccine safety issues.

Vaccine Safety Update. An update on vaccine safety began with a presentation by Dr. Bruce Gellin on the status of the work by the Federal Immunization Safety Task Force. This was followed by an update from the chair of the NVAC Vaccine Safety working group, Dr. Andy Pavia. Dr. Pavia reviewed the charge of the working group, as well as how the group is addressing the CDC Immunization Safety Office (ISO) Scientific Agenda. Dr. Pavia indicated that public engagement related to the development of this Agenda will be occurring soon, with information gained through this process helping develop recommendations to CDC ISO. Mr. Ed Moreno from the Keystone Center, a non-profit agency that aids in performing evaluations related to public health, explained how his agency will facilitate these public engagement sessions, with a final report anticipated early in 2009.

Adult Immunization Working Group. Dr. Richard Clover gave an update on the Adult Immunization working group. To date, this group has reviewed adult immunization programs through many areas of the Department of Health and Human Services, and is developing an inventory of issues that need to be addressed. Further review of adult immunization practices and issues is underway, and a partnership between the Adult

Immunization and Vaccine Finance working groups will be starting soon, to address adult immunization financing issues.

Dr. L.J. Tan of the American Medical Association gave a presentation on the Draft Recommendations related to Adult Vaccine Financing that will be voted on by the AMA Council on Science and Public Health. While the timeframe for this vote did not allow formal comments from NVAC to be provided, Dr. Tan asked that NVAC members provide individual feedback on the proposed recommendations if they were able.

Immunization Information Systems (IIS) follow-up. Dr. Alan Hinman presented recommendations from the NVAC working group in IIS to enhance the use of Immunization Information Systems. These recommendations are the latest from the working group and supplement earlier recommendations adopted by NVAC. They encompass the areas of Policy and Regulatory Approaches, Provider Incentives, and Financial Support. The recommendations were reviewed and discussed by NVAC, and were adopted by a unanimous vote. A summary document, "Enhancing Participation in Immunization Information Systems" is attached to this letter for your review and approval.

National Vaccine Plan update. The final agenda item for the first day of the meeting addressed the development of the new National Vaccine Plan, by Dr. Ray Strikas. Dr. Strikas reviewed the IOM report that contained recommendations for an update of the Plan, a meeting that was held to discuss the process for this update, and a series of interviews with NVAC members to develop additional information for the update. RAND is providing consultation in the development of the Plan, and initial diagrams of process flow developed by RAND were shown, to help outline the interactions that must be considered during this update process. Finally, Dr. Strikas laid out the role of NVAC in this update, including providing input throughout the process, and reviewing the report as it is developed.

Federal Agency Reports. The second day of the meeting opened with reports from representatives of various agencies and departments.

Healthcare Acquired Infection (HAI) Task Force. These reports were followed by two presentations on the HAI Task Force. Dr. Donald Wright provided an overview of the work of this task force and outlined how NVAC can aid in these activities, through encouragement of seasonal influenza and occupational hazard vaccinations for healthcare workers, and support for the development of vaccines for the primary HAIs. Dr. Barbara Mulach from NIH presented information on possible vaccine candidates through this initiative.

Vaccine Supply and Stockpile Issues. Next was a series of presentations related to vaccine supply and stockpile, starting with an overview of the critical issues given by Dr. Lance Rodewald. Dr. Gregory Wallace provided information about the current stockpile of Vaccines for Children vaccines, which led to a demonstration of a computer modeling program that has been developed at CDC to aid in planning vaccine stockpile logistics.

Dr. Charles Rupprecht gave an update on the current state of rabies vaccine supply issues and implications from the shortage of rabies vaccine. An Ad Hoc working group has been created to address these issues, and this group has developed draft guidelines regarding rabies vaccine stockpiling that NVAC has been asked to give input on.

Influenza update. The final agenda item for the meeting was a series of topical issues related to influenza vaccination. Dr. Jeanne Santoli gave an update on the changes to the ACIP recommendations for influenza vaccination for the 2008-2009 influenza season. With 11 different influenza vaccine products available this season, it was estimated that the total capacity would be 143-146 million doses, with approximately 20 million doses that are thimerosal free. Dr. Kris Sheedy presented study results indicating that while people are aware of the health consequences of influenza, many do not feel concerned for themselves, indicating that appropriate messages must be tailored to improve influenza vaccination awareness and levels. She followed this up with preliminary presentations on CDC promotional campaigns for influenza vaccination for the upcoming influenza season. Dr. Bruce Gellin reviewed recent charges for new and better influenza vaccines, and the ways in which development of vaccines that are more targeted in the populations they address can be beneficial. He noted that the landscape of vaccination is becoming more complex. Dr. Mark Steinhoff presented data from a recently published study on the benefits of maternal influenza vaccination to the health of the infants. His research showed that infants less than six months, for whom there is no licensed influenza vaccine, experience dramatic reductions in respiratory illness and clinic visits when their mothers are vaccinated for influenza during pregnancy.

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. I would be pleased if you could attend our next meeting which is scheduled on February 5-6, 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, MD, MPH
Chair, National Vaccine Advisory Committee

Enclosures