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March 11, 2003

Richard Carmona, M.D.
Acting Assistant Secretary for Health
Department of Health and Human Services
200 Independent Avenue, SW, Rm 716G
Washington, DC 20201

Dear Dr. Carmona:

The National Vaccine Advisory Committee (NVAC) convened on February 4-5, 2003 for its regularly scheduled meeting. The Committee, established by 1986 legislation, advises the Department on major programmatic issues concerning vaccines and immunization policy, and represents major stakeholders in the public and private sectors. The following report summarizes our deliberations and recommendations, and is submitted to you in your role as Acting Director of the National Vaccine Program and Assistant Secretary for Health. A copy of the agenda is enclosed. In addition, given the critical importance of immunizations in public health and bioterrorism preparedness, I hope to meet with you before the next NVAC meeting to discuss our priorities and objectives.

A major topic at the meeting was the national smallpox vaccination program. Presentations were given by federal and state health department and military representatives, and the initial report of the Institute of Medicine (IOM) Committee on Smallpox Vaccination Program Implementation was summarized. While the NVAC did not reach any conclusions and at this time has no recommendations to the Department, several important points were evident. They include the immense effort and comprehensive planning by the Centers for Disease Control and Prevention (CDC), difficulty and challenges that state health departments are experiencing in rapid implementation, need for a comprehensive compensation program, and the possible unintended negative consequences of the smallpox program on immunization delivery and other major public health programs. Several members expressed concern that whereas the original intent of the CDC program, which is consistent with the recommendations of the Advisory Committee on Immunization Practices (ACIP), was to vaccinate a cadre of health care workers to staff hospital's smallpox response teams, the emphasis had changed to protection for those who are at risk of possible exposure. Once the transcript of the meeting is available, Dr. Gellin, the Director of the National Vaccine Program Office (NVPO) and I can, if desired, compile a summary of the proceedings and discussions on this topic.

A related question on which the Committee made a recommendation, after initially tabling the issue, concerned the downselection process by the Department of the new tissue culture-derived smallpox vaccines, i.e. Acambis1000 and Acambis2000. Dr. Donlon of the Office of Public Health Preparedness presented a detailed summary of the December 13, 2002 meeting of the Joint HHS/DOD Vaccine Downselection Working Group. NVAC is represented in this group by three members. The NVAC recommendation to the Department, which was unanimously approved (11-0), is as follows:

> "Noting the absence of complete data with which to address the question of vaccine selection, the Committee concludes that proceeding with the development of Acambis2000 is reasonable".

Other developments were as follows:

1. Vaccine Supply. In 2001, the Department requested that NVAC consider strategies for strengthening the nation's supply of routinely recommended vaccines. At that time, shortages of multiple childhood vaccines were developing and led to a national crisis that prompted Congressional concern and a resulting GAO report. In February 2002 NVAC/NVPO held a two-day symposium to explore the issues, which was the basis the NVAC report in October to the Department. This report has been posted on the NVPO website and distributed widely for review to the immunization community.

   At the meeting, plans for publication of the NVAC report were reviewed. A manuscript based on this report has been prepared for submission to a peer-review journal and is in the final stages of review and editing. A copy of the report is enclosed. To publicize further the report, a "Notice to Readers" in *Morbidity and Mortality Report* is anticipated. In addition, the proceedings of the February 2002 symposium are scheduled for publication later this year in a supplement of *Clinical Infectious Diseases*. As previously noted in my earlier letter to Dr. Slater summarizing the October 8-9 meeting, the NVAC Work Group on Vaccine Supply will remain active to advise the Department on issues concerning supply, including the expansion of the national vaccine stockpile.

2. Immunization registries. Support of the development and appropriate use of registries continues to be a major priority of the Committee. Dr. Slater reported to the Committee that the Department is exploring whether Vaccines for Children (VFC) funding can be used for registry development. We look forward to a Department policy on this question.

The Committee passed a resolution that the CDC should "continue working with its partners to identify and disseminate best practices for registry support of immunization programs, such as those in the *Registry Standards of Excellence in Support of An Immunization Program"*, developed by the American Immunization Registry Association. A copy of the NVAC resolution with background information is enclosed. The six standards of excellence include vaccine management, provider quality assurance, service delivery, consumer information, surveillance and assessment. The *Registry Standards of Excellence* that delineate these standards include a self-assessment tool for immunization program staff and complements existing manuals and statements on the functioning and development of registries. A copy of this document can be provided by Dr. Gellin.

3. Polio eradication. The NVAC earlier agreed to serve as the national certifying organization for global poliovirus eradication, including laboratory containment of wild-type poliovirus. A work group will be formed under the leadership of Dr. Ann Arvin, an NVAC member, and Dr. Walter Dowdle of the Task Force for Child Survival.

4. Polio vaccine stockpile. The problems in maintaining an OPV stockpile were reviewed by staff of the National Immunization Program at CDC. A polio vaccine stockpile is necessary in case of the introduction of wild-type poliovirus in the United States, since OPV remains the vaccine of choice for control and eradication of circulating wild-type virus and is no longer manufactured in this country. A joint NVAC-ACIP Work Group to advise NVAC on the development of an appropriate stockpile will be formed.

5. IOM activities. The findings of the most recent report of the IOM Immunization Safety Review Committee, *SV40 Contamination of Polio Vaccine and Cancer*, were presented. One of the recommendations is that the "appropriate federal agencies develop a Vaccine Contamination Prevention and Response Plan", which the Interagency Vaccine Group is preparing.

   The NVAC discussed future recommendations for topics for this IOM Committee and proposed to the Interagency Vaccine Group that the next one should be "Evaluation of Current Mechanisms for Determining Acute and Delayed Onset Adverse Events".

   This committee, which was established by a joint CDC-NIH contract in late 2000 to review vaccine safety issues has issued five reviews and a sixth is anticipated shortly. Their work highlights the importance of vaccine safety and need for an updated action plan by the Department. NVAC will be working with NVPO on this initiative.

6. Immunization standards. Both the *Standards* for adult and for children and adolescents, which NVAC previously prepared and have been widely endorsed by major partner organizations, are scheduled for publication in peer-review journals later this year. These *Standards* also will be publicized by NVPO and CDC on their websites and in *Morbidity and Mortality Weekly Report*. They will update the national guidelines that were developed a decade ago and have served to enhance immunization delivery.

7 Center for Medicare and Medicaid Services (CMS). The Committee representative from CMS summarized the 2003 final rule for physician payment for vaccine administration. The Committee continues to express serious concerns about the lack of specified compensation for physician work in vaccine administration, as noted in earlier reports to the Assistant Secretary. Standards for vaccine administration for both adults and children stress the need for effective communication about vaccine benefits and risks. The lack of compensation for such services creates a barrier to successful vaccine delivery at a time when public concerns about vaccine safety are increasing. The Committee has requested a presentation by CMS at its next meeting.

8. Work Group on Public Health Options for Implementing Immunization Recommendations. A summary of the proposed report by the Work Group was presented. The working group was formed several years ago to provide guidelines for state health departments to use in their decision-making about immunization requirements, such as for school entry. The report is to be prepared this spring and then will be reviewed at the NVAC June meeting.

9. Thimerosal litigation. The premise that thimerosal in vaccines is responsible for the increase in childhood developmental disorders, including autism, has led to a number of individual and class action law suits. Presentations were given, reviewing the status of the litigation in the Vaccine Injury Compensation Program, relevant legislation, and the report of the Advisory Committee on Childhood Vaccines. This issue is critically important to our national immunization programs and will be followed closely by the NVAC. A major concern in the discovery process of the litigation is the possible negative impact on the integrity and viability of the scientific process in the national vaccine safety monitoring system and clinical vaccine research. Dr. Gellin has been asked to convey the Committee's concerns to the Administration and relevant organizations, such as the IOM.

10. Workshops. The NVAC Subcommittee on Future Vaccines proposed two workshops. One is "Assessment of Neonatal Immunization Vaccination with Current and Future Vaccines" and the other concerns pneumococcal vaccination of elderly and high risk adults. Proposals have been submitted to the NVPO for Unmet Needs funding. The Subcommittee also is preparing a status report on cytomegalovirus (CMV) vaccine development in follow-up of the NVPO-sponsored CMV workshop several years ago.

Other agenda issues presented at the meeting included the vaccine and immunization components of the Department's Global Health Agenda and Project Bioshield, recent developments concerning immunization programs emanating from bioterrorism preparedness, and the resulting coordination between Homeland Security and HHS. The Committee anticipates further presentations on these topics.

Our next meeting is June 3-4, 2003. We look forward to working with you in your capacity as Acting Assistant Secretary of Health and Director of the National Vaccine Program. Dr. Gellin and I hope to meet with you in advance of the meeting to discuss the complex issues and challenges that the Committee is considering.

If you have questions about the deliberations and recommendations of NVAC, please contact Dr. Gellin or me at your convenience.

Sincerely yours,

Georges Peter, M.D.
Chairman
National Vaccine Advisory Committee

Professor of Pediatrics
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GP/cs

Enclosures (3)

cc: Bruce G. Gellin, M.D., M.P.H.
Members of NVAC