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June 24, 2003

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

Dear Dr. Carmona:

The National Vaccine Advisory Committee (NVAC), as you know, held its regularly scheduled meeting on June 3-4, 2003 and reviewed current critical issues in our national vaccine programs and policies. The Committee most appreciates the support you expressed for the activities and expanding work of the National Vaccine Program Office (NVPO) in supporting the programmatic coordination and necessary initiatives in the major public health priority of immunizations, and resulting role of the committee on advisory responsibilities. Your leadership as the Director of the National Vaccine Program (NVP) is an essential element in the Department's immunization programs.

During our two-day meeting, presentations and resulting discussions on a wide range of issues were held. A copy of the agenda is enclosed. These issues included smallpox vaccination program and bioterrorism preparedness; vaccine supply; the National Influenza Vaccine Summit; a proposal for an initiative to enhance public participation in immunization decision-making; economic evaluation of the nation's childhood immunization program; plans to develop a report on initiatives to enhance adult immunization rates and reduce ethnic and racial disparities; the Institute of Medicine (IOM) Safety Review Committee; funding of immunization registries to enhance timely fulfillment of the Healthy People 2010 objectives; and the continuing lack of recognition by the Center for Medicare and Medicaid Services (CMS) of the need for compensation for physician work in vaccine administration. Dr. Gellin and I discussed this latter issue with you in some detail in our May 13 meeting. Any efforts you may be able to take with Mr. Scully of CMS to expedite satisfactory resolution of this problem would be most helpful.

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I am particularly pleased in recent months by the work of the NVAC subcommittees and the increasing number of workgroups established since Dr. Gellin became the NVPO Director. These activities underscore the scope and significance of the current challenges, importance of NVAC, and resulting need to consider expanding the size of the Committee to broaden the stakeholder representation and expertise. As Dr. Gellin has or will discuss with you, this summer may be an appropriate time to review the NVAC Charter and consider changes to help us respond expeditiously and effectively.

The major developments and recommendations of the meeting are summarized as follows:

1. Smallpox vaccination program. Presentations by the IOM Committee, the General Accounting Office, Department of Defense, National Immunization Program (NIP) and the Association of State and Territorial Health Officials (ASTHO) resulted in extensive discussion and a major recommendation. Whereas the Committee commends the Centers for Disease Control and Prevention for its extensive and competent response to the threat of a bioterrorist smallpox attack, the Smallpox Vaccination Program has encountered a number of problems and has had limited success in implementation. As a result, the Committee unanimously passed the following resolution:

"The National Vaccine Advisory Committee reaffirms the necessity for the nation's health system to be prepared for biological threats, man-made or natural, and encourages continued efforts in this regard. With respect to the smallpox vaccination, the Committee recommends that the Assistant Secretary for Health in consultation with the Department's Office of Public Health Emergency Preparedness consider the recommendations of ASTHO regarding the routine smallpox vaccination program and that further smallpox vaccinations, beyond those of public health response and vaccination teams, should be delayed until a national consensus is developed on appropriate next steps."

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The specific ASTHO recommendations presented to the Committee by Dr. Williamson, State Health Official of the Alabama Department of Health and an NVAC member, are as follows:

- A national consensus on who should be asked to consider voluntary vaccination at this point in time - and why
  - A clear articulation of the best currently available intelligence information as to the potential risk of smallpox to the nation
  - A clear statement of all currently known benefits and risks of smallpox vaccination
  - A clear statement outlining all liability and compensation protections that now exist under federal legislation
  - Sufficient resources for public health preparedness against all possible threats and emergencies, including smallpox
2. Vaccine supply. While the recent shortages have resolved, the underlying problems that led to those shortages warrant continued attention in order to prevent recurrences. Dr. Gellin reviewed for the Committee the considerable progress and planning in the Administration's initial efforts to address these problems. The October 2002 NVAC report to the Department has now been prepared as a manuscript and submitted for consideration to the *Journal of the American Medical Association*. In further follow-up, the NVAC Workgroup on Vaccine Supply will be reconvened in the fall and is proposing a meeting to review the progress and continuing challenges since the Workgroup convened a two-day conference in February 2002.
3. "Economic Evaluation of Routine Childhood Immunizations in the United States, 2001". The preliminary results of an analysis by the Health Services Research and Evaluation Branch of the NIP demonstrate that our national childhood immunization program is not only highly effective but also very economical. The Program saves approximately \$10.5 billion in direct medical costs and \$42 billion from the societal perspective for each birth cohort. The direct and societal benefit costs ratios are \$6.3 and \$18.4, respectively.

These data provide an appropriate context in which the Committee will begin a detailed discussion of vaccine financing at the October meeting, including presentation of the report of IOM Committee on Vaccine Purchase Financing.

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4. Pneumococcal vaccine workshop. A meeting being organized by the NVAC Subcommittee on Future Vaccines to evaluate the possible use of pneumococcal conjugate vaccine in adults will be held on September 9-10, 2003.
5. Cytomegalovirus (CMV) vaccine. A report, "Vaccine Development to Prevent Cytomegalovirus Disease: Report of the NVAC", in follow-up of the NVAC/NVPO workshop on this subject is near completion. The Subcommittee on Future Vaccines concludes that a CMV vaccine to prevent congenital infections, neurological damage and deafness is a high priority as recommended previously by the IOM and necessitates the strong support of government agencies, including funding of appropriate studies by the National Institutes of Health. We expect that the report will be finalized by the Committee in October and forwarded to you for distribution to the agencies.
6. Immunization Standards. Both the *Standards* for adult and for childhood and adolescents are in press in peer-review journals. This summer the adult standards will be published in the *American Journal of Preventive Medicine* and the childhood standards will be published in *Pediatrics*.
7. Workgroup on Public Health Options for Implementing Immunization Recommendations. A preliminary report was reviewed by the Workgroup and plans made for revision during the summer with the goal of presentation of a report at the October NVAC meeting.
8. Workgroups. Four new workgroups have or will be established. Specific issues include evaluation of the polio vaccine stockpile, poliovirus laboratory containment (in conjunction with NVAC responsibilities to serve as the national certifying organization in global poliovirus eradication), the national plans for influenza pandemic preparedness, and anthrax vaccine safety monitoring. In addition, a workgroup on the proposal for an initiative to enhance public participation immunization decision-making likely will be formed, pending further review and discussion with the agencies, the Advisory Committee on Immunization Practices (ACIP) and NVAC leadership with Dr. Gellin.

Thank you again for your presentation at our meeting. We appreciate your leadership and advocacy on the multiple issues the Committee has been asked to consider. Dr. Gellin will provide you with further details and information on our activities and recommendations, including a memorandum on immunization registry funding.

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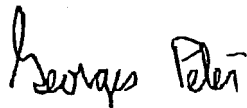
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During the summer, I will be on a medical leave-of-absence for surgery beginning in mid-July. I anticipate returning in time for the next Committee meeting. In my absence, Dr. Charles M. Helms, a current NVAC member, has agreed to be the Acting Chair. He is Professor of Medicine at the University of Iowa and Chief of Staff of the University Hospitals and Clinics, and is highly experienced in national vaccine policy and programs, having previously served on the ACIP and as a congressional staff member during a sabbatical year as a Robert Wood Johnson Foundation scholar.

Our next meeting is October 7-8, 2003 in Washington. We hope very much that you will again meet with us.

Thank you.

Sincerely yours,



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

Professor of Pediatrics  
Vice Chair for Faculty Affairs  
Department of Pediatrics  
Brown Medical School

GP/cs

Enclosure

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