



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

CHARTER

NATIONAL VACCINE ADVISORY COMMITTEE

Purpose

The Secretary of Health and Human Services is mandated under Section 2101 of the Public Health Service (PHS) Act (42 U.S.C. Section 300aa-1) to establish a National Vaccine Program (NVP) to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The National Vaccine Advisory Committee (NVAC or the Committee) shall advise and make recommendations to the Director of the NVP on matters related to the Program's responsibilities. Pursuant to the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (42 FR 61318, dated December 2, 1977; as amended in 52 FR 23502, dated June 22, 1987), the Assistant Secretary for Health (ASH) shall serve as Director of the NVP.

Authority

Section 2105 of the PHS Act, as amended (42 U.S.C. Section 300aa-5). The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

Function

The Committee shall:

- (1) Study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States.
- (2) Recommend research priorities and other measures the Director of the NVP should take to enhance the safety and efficacy of vaccines.
- (3) Advise the Director of the NVP in the implementation of Sections 2102 and 2103 of the PHS Act.
- (4) Identify annually for the Director of the NVP the most important areas of governmental and non-governmental cooperation that should be considered in implementing Sections 2101 and 2103 of the PHS Act.

Structure

The Committee shall consist of 17 voting members. There will be 15 public members, including the Chair, who will be selected from individuals who are engaged in vaccine research or the manufacture of vaccines, or who are physicians, members of parent organizations concerned with immunizations, representatives of State or local health agencies or public health organizations. The 15 public members shall be classified as special Government employees (SGEs). There will be two members who are designated to serve as representatives of the vaccine manufacturing industry who are engaged in vaccine research or the manufacture of vaccines. Committee members shall be appointed by the Director of the NVP, in consultation with the National Academy of Sciences; affected entities of the vaccine industry will be consulted, as well, for selection of the two representative members.

Composition of the Committee shall include ten non-voting *ex officio* members selected to represent various Federal agencies which have an interest and/or involvement in the development, testing, licensing, production, procurement, distribution and/or production of vaccines and/or vaccine research. The non-voting *ex-officio* members shall include: Director for Health and Nutrition, Agency for International Development; Director, Centers for Disease Control and Prevention; Director, Food and Nutrition Service, U.S. Department of Agriculture; Deputy Assistant Secretary for Clinical Services, Office of the Assistant Secretary for Health Affairs, Department of Defense; Commissioner of Food and Drugs; Administrator, Centers for Medicare and Medicaid Services; Chief Medical Officer, Health Resources and Services Administration; Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration; Director, National Institutes of Health; and Chief of Public Health, Department of Veterans Affairs. For those positions that are identified to be occupied by an agency head, the designated official can select their delegated representative. There also shall be individuals serving as a non-voting liaison representative for the following entities: America's Health Insurance Plans, the Advisory Commission on Childhood Vaccines, the Vaccines and Related Biological Products Advisory Committee, the Advisory Committee on Immunization Practices, the Public Health Agency of Canada, the Ministry of Health of Mexico, and the Department of Health of the United Kingdom. The membership may be extended to include other organizations and/or interest groups as it is deemed necessary by the Director of the NVP to accomplish the established mission of the Committee.

Members shall be invited to serve for overlapping terms of up to four years, except any member appointed to fill the vacancy of an unexpired term shall be appointed for the remainder of that term. Terms of more than two years are contingent upon renewal of the Committee by appropriate action prior to its termination. A member may serve after the expiration of their term until their successor has taken office, but no longer than 180 days.

In carrying out its function, the Committee may establish subcommittees composed of members of the parent committee, as well as other individuals, with approval of the Director of NVP (or designee), (e.g., individuals from organizations and the public at large who are concerned and knowledgeable about immunizations and other topics pertaining to the NVAC mission). The Department Committee Management Officer will be notified upon establishment of each subcommittee, and will be provided information on its name, membership, function, and estimated frequency of meetings. Management and support services for Committee activities shall be provided by the National Vaccine Program Office.

Meetings

Meetings shall be held approximately three times per year. Meetings shall be held at the call of the designated Federal officer (DFO), who is responsible for developing the meeting agenda. Development of the meeting agenda may be done in collaboration with the Committee Chair. The DFO or other official to whom the authority has been delegated shall be present at all meetings of the full Committee and any subcommittees/working groups that have been assembled to assist the Committee. A quorum for the conduct of business by the full Committee shall consist of a majority of the Committee's voting members.

Meetings shall be open to the public except as determined otherwise by the Secretary, or other official to whom the authority has been delegated, in accordance with the guidelines under Government in the Sunshine Act at 5 U.S.C. 552b(c) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public.

Meetings shall be conducted and records of the proceedings kept, as required by applicable laws and Departmental regulations.

Compensation

Members who are not full-time Federal employees shall be paid at a rate not to exceed \$250.00 per day, plus per diem and travel expenses, as authorized by Section 5703, Title 5 U.S.C., as amended for persons employed intermittently in the Government service. Members who are officers or employees of the United States Government shall not receive compensation for service on the Committee. Members who serve in a representative status shall serve without compensation, pursuant to an advance written agreement, but may be allowed per diem and travel expenses for all Government-directed travel.

Annual Cost Estimate

The estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is \$210,250. The estimate of annual person-years of staff support required is 2.45, at an estimated cost of \$308,772.

Reports

When it is determined that a meeting shall be closed or partially closed to the public, as determined by the Secretary or other official to whom the authority has been delegated, in accordance with Government in the Sunshine Act at 5 U.S.C. 552b(c) and the Federal Advisory Committee Act, then a report shall be prepared that will contain, at a minimum, a list of members and their business addresses; the Committees's functions, dates, places of meetings, and a summary of the topics discussed and/or Committee business conducted and the resulting recommendations made. A copy of the report shall be provided to the Department Committee Management Officer.

Termination Date

Unless renewed by the appropriate action prior to the date stipulated, the activities of the National Vaccine Advisory Committee will be terminated on July 30, 2009.

Approved:

07/23/07
Date



Assistant Secretary for Health
Director, National Vaccine Program