

CHARTER
NATIONAL VACCINE ADVISORY COMMITTEE

Authority

Section 2105 of the Public Health Service (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.), which sets forth standards for the formation and use of advisory committees.

Objectives and Scope of Activities

The Secretary of Health and Human Services is mandated under Section 2101 of the 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. Pursuant to the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, the Assistant Secretary for Health (ASH) shall serve as Director of the NVP (42 FR 61318, dated Dec. 2, 1977; as amended in 52 FR 23502, dated June 22, 1987) and shall provide advice and counsel on public health and science issues to the Secretary (60 FR 56606-06, dated Nov. 9, 1995). 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.

Description of Duties

The functions of the Committee as stated in Section 2105 of the Public Health Service (PHS) Act are as follows:

- (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.

Official to Whom the Committee Reports

As stipulated in the authorizing legislation, under Section 2105 of the Public Health Service Act, the Committee reports to the Director of the NVP. The Assistant Secretary for Health has been assigned by the Secretary to serve as Director of the NVP.

Support

Management and support services for Committee activities are provided by the National Vaccine Program Office (NVPO), which is a program office within the Office of the Assistant Secretary for Health in the Office of the Secretary of the Department of Health and Human Services.

Estimated Annual Operating Costs and Staff Years

The estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is \$573,500. The estimate of annual person-years of staff support required is 3.3, at an estimated cost of \$366,000.

Designated Federal Officer

The Director of the NVPO will serve as the designated Federal officer for the Committee. In the event that the DFO cannot fulfill the assigned responsibilities for the Committee, then the Director of the NVP or designee will temporarily appoint one or more permanent full-time or part-time program staff to carry out the assigned duties.

The DFO will schedule and approve for all meetings of the parent Committee and respective subcommittees to be held. The DFO will prepare and approve all meeting agendas; development of the meeting agenda can be done in collaboration with the Committee Chair. The DFO or other official to whom the authority has been delegated will be present at all meetings of the full Committee and any subcommittees/working groups that have been assembled to assist the Committee. The DFO has authority to adjourn meetings, when it is determined to be in the public interest, and may also chair the committee meetings when directed to do so by the Director of the NVP or designee.

Estimated Number and Frequency of Meetings

Meetings will be held, at a minimum, three times per year; meetings will be held approximately every four months. 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 guidelines under Government in the Sunshine Act at 5 U.S.C. 552b(c) and the Federal Advisory Committee Act. Notice of all meetings is provided to the public 15 calendar days prior to the meeting. Meetings will be conducted and records of the proceedings will be kept, as required by applicable laws and Departmental policies.

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When it is determined by the Secretary or designee that a meeting will be closed or partially closed to the public, in accordance with stipulations of Government in the Sunshine Act, 5 U.S.C. 552b(c), then a report will be prepared that includes, at a minimum, a list of the members and their business addresses, the Committee's functions, date and place of the meeting, and a summary of the Committee's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

Duration

The National Vaccine Advisory Committee is statutorily mandated; no specific end date has been established.

Termination

Unless renewed by appropriate action, the charter for the Committee will be terminated two years from the date it is filed.

Membership and Designation

The Committee consists of 17 voting members. The Committee structure is composed of 15 individuals who are appointed to serve as public members, including the Chair, and two individuals who are designated to serve as official representatives of the vaccine manufacturing industry. The public members are 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 public members are classified as special Government employees (SGEs). The two members who are designated to serve as representatives of the vaccine manufacturing industry are selected from individuals who are engaged in vaccine research or the manufacture of vaccines. Committee members are 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 includes 13 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: Administrator, Centers for Medicare and Medicaid Services; Chief Medical Officer, Health Resources and Services Administration; Chief of Public Health, Department of Veterans Affairs; Commissioner of Food and Drug Administration; Director for Health and Nutrition, U.S. Agency for International Development; Director, Centers for Disease Control and Prevention; Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau of the Health Resources and Services Administration; Director, National Institutes of Health; Director, Indian Health Services; Director, Agency for Healthcare Research and Quality; Deputy Assistant Secretary for Clinical Services in the Office of the Assistant Secretary for Health Affairs of the Department of Defense; and Deputy Secretary, U.S. Department of Agriculture; and Director, Office of Biomedical Advanced Research and Development Authority (BARDA) in the HHS Office of the Assistant Secretary for Preparedness and Response. For those positions that are identified to be occupied by an agency head, the

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designated official may select their delegated representative. There also shall be individuals serving as a non-voting liaison representative for the following entities: Advisory Commission on Childhood Vaccines; Advisory Committee on Immunization Practices, AIM (Association of Immunization Managers); America's Health Insurance Plans; American Immunization Registry Association (AIRA); Association of State and Territorial Health Officials; Department of Health of the United Kingdom; Ministry of Health of Mexico; National Association of County and City Health Officials; National Biodefense Science Board; Pan American Health Organization; Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria; Public Health Agency of Canada; and the Vaccines and Related Biological Products Advisory Committee. The membership may be extended to include other organizations and/or interest groups as it is deemed necessary by the Director of NVP or designee to accomplish the established mission of the Committee.

Members are invited to serve for overlapping terms of up to four years, except any member appointed to fill the vacancy of an unexpired term will be appointed to serve 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.

The Chair shall be appointed for a three year term unless otherwise specified. The Chair will be chosen from among persons who preferably have had at least one year experience as a voting member and, preferably, have demonstrated ability both to lead the work of similar bodies and to work effectively in partnership with federal agencies and partner organizations.

The public voting members of the parent committee are authorized to receive compensation for services provided at public meetings of the Committee. These individuals 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. All other services that are performed by the public voting members outside the Committee meetings shall be provided without compensation, pursuant to an advance written agreement. Individuals who are appointed to serve as official representative members of the vaccine manufacturing industry or any particular interest group or business sector will serve without compensation. The representative members may be allowed per diem and any applicable expenses for all travel performed that is related to conducting business for the Committee.

Subcommittees/Working Groups

In carrying out its function, the Committee may establish subcommittees and/or working groups composed of members of the parent committee, as well as other individuals, with approval and/or recommendation 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 or working group, and will be provided information on its name, membership, function, and estimated frequency of meetings. All reports and recommendations of the subcommittee or work group must be reported back to the full Committee for action. No activity of the subcommittee or working group can be given directly to the Director of the NVP without being provided for discussion by the full committee.

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Recordkeeping

Records of the Committee and the respective subcommittees or subgroups will be handled in accordance with General Schedule 26, Item 2 or other approved agency records disposition scheduled. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date: July 30, 2015

Approved:

Date

Acting Assistant Secretary for Health
Acting Director, National Vaccine Program