Advisory Committee on Immunization Practices Policies and Procedures

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Introduction

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee, composed of medical and public health experts, that provides advice and guidance to the Director of the Centers for Disease Control and Prevention (CDC) and the Secretary of the Department of Health and Human Services (HHS) on the most effective means to prevent vaccine-preventable diseases in the United States. ACIP's guidance includes the use of vaccines, and may also include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available. In addition, ACIP has a statutory authority for the Vaccines for Children (VFC) program; ACIP has sole responsibility and authority to determine the vaccines, number of doses, schedule and contraindications for the VFC program.

ACIP develops written recommendations—subject to the approval of the CDC Director—for the routine administration of vaccines to both pediatric and adult populations. To inform its advice to the CDC Director, ACIP considers disease epidemiology and burden of disease, vaccine efficacy and effectiveness, vaccine safety, the quality of evidence reviewed, economic analyses, and implementation issues. The overall goals of ACIP are to provide advice that will assist CDC and HHS in reducing the incidence of vaccine preventable diseases and to increase the safe usage of vaccines and related biological products, including active and passive immunoprophylaxis. The target populations for ACIP recommendations are public and private health care providers who administer vaccines, public and private officials who make vaccine policy, and the general public.

Organization of this Document

This document is intended to serve as a reference for ACIP members (and interested members of the general public) about ACIP's structure and functions. It is organized into the following sections:

- ACIP Structure: This section describes the individuals and groups who make up ACIP.
- ACIP Functions: This section provides an overview of the activities and objectives of ACIP.
- ACIP Roles and Responsibilities: This section contains descriptions of the roles and responsibilities of ACIP members in carrying out ACIP's functions.
- ACIP Membership Procedures: This section details the process for nomination, selection, and orientation of new ACIP members.

ACIP Structure

ACIP is a Federal Advisory Committee; the Federal Advisory Committee Act of 1972 requires all such committees to have a committee charter. The charter marks the formal establishment of the committee, and the language of the charter specifies the committee's mission or charge and includes operational characteristics, such as the number of members and the types of expertise required, the number of meetings to be held per year, and the projected yearly operating cost for the committee. Any proposed changes to the charter are discussed by the Steering Committee. The ACIP Secretariat is responsible for renewing the charter every 2 years, and submitting amendments to the Secretary of Health and Human Services, who is responsible for reviewing and approving the charter renewal.

ACIP's charter is available at https://www.cdc.gov/vaccines/acip/committee/charter.html.

Charge to Members

Within ACIP's charter, the formal Objective and Scope of Activities are:

"The Secretary, Department of Health and Human Services (HHS), and by delegation the Director, Centers for Disease Control and Prevention (CDC), are authorized under Section 311 and Section 317 of the Public Health Service Act, [42 U.S.C. §243 and 42 U.S.C. §247b], as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs."

Members of ACIP have a responsibility to provide CDC and HHS with high quality, well considered advice and recommendations. ACIP members play a critical role in ensuring the reputation of ACIP as a nationally and internationally recognized advisory group in the field of immunization. ACIP members are committed to the development and improvement of public health policies.

Member Types

ACIP comprises 15 voting members, eight *ex officio* members, and 31 liaison representatives (see the Table), who function under a Chair and Vice Chair and are guided by a Steering Committee.

ACIP Membership must include at least 20% minority representation. The following is the official description of qualifying U.S. minority group candidates provided by Federal Advisory Committee Management Branch (FACMB)/Management Analysis and Services Office (MASO):

- Black or African American
- Hispanic
- American Indian/Alaska native
- Asian (origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. It includes "Asian Indian," "Chinese," "Filipino," "Korean," "Japanese," "Vietnamese," and "Other Asian.")

Voting Members

Voting members serve overlapping terms of 4 years. Voting members are identified by the ACIP Steering Committee, and selected and appointed by the Secretary of HHS. Members fall into the following two categories:

- **Medical Professional Members (14).** ACIP includes 14 members representing clinical medical fields (physician, nurse, nurse practitioner) and/or public health professionals, e.g., State Health Department staff or epidemiologists. These positions are held by technically qualified people trained in a clinical medical field who possess in-depth knowledge of vaccines and immunization. Candidates for this position may be recommended by a professional medical organization or other interested parties. ACIP also welcomes self-nominated candidates possessing the required technical knowledge and experience.
- **Lay Member: Consumer Representative (one).** ACIP must include a consumer representative as one of the 15 voting members of the committee. This position is held by a technically qualified person knowledgeable about consumer perspectives and/or social and community aspects of immunization programs. Candidates for this position may be recommended by a consortium of consumer-oriented

organizations, an individual consumer-oriented organization, or other interested parties. ACIP also welcomes self-nominated candidates possessing the required technical knowledge and experience.

Ex Officio and Liaison Members

In addition to the voting members, the Committee has eight *ex officio* members (who generally do not vote, but may be designated to vote in specific circumstances by the Executive Secretary) from other federal agencies and 31 non-voting liaison representatives from professional societies and organizations responsible for the development and execution of immunization programs for children and adults. *Ex officio* members and liaison representatives are expected to represent the position and views of their sponsoring organizations, and to contribute to Committee discussions when issues of importance to their organization are being discussed and when they possess information important to the discussion. *Ex officio* and liaison members also may serve on Work Groups to provide expert advice and apprise the Work Group of the position their organization endorses.

Ex officio members representing (and financially supported by) other federal agencies/departments are appointed based on a written document which outlines how the other agency/department can contribute to the quality of ACIP deliberations and decisions and/or enhance the implementation of ACIP recommendations.

Appointments of liaison representatives, primarily from professional organizations, are based upon written requests from organizations which document the commitment of the organization to providing expert input into ACIP decision-making process, travel and per diem support to their representative, and strongly encouraging their membership to adopt ACIP recommendations. Because of space and time limitations at meetings, liaison representatives must represent organizations that have broad immunization interests and that represent large constituencies. Groups that represent more narrow interests (e.g., interest in a single disease or vaccine) or small constituencies (e.g., organ transplant patients) are invited to participate in ACIP activities on an ad hoc basis whenever issues of interest and concern are being discussed rather than requesting liaison representation.

ACIP Leadership

Chairmanship and Vice Chairmanship

Every 3 years the ACIP Secretariat identifies an ACIP Chair from the ACIP members who have served at least one year. The ACIP Chair serves a 3-year term, as defined in ACIP Charter, and must be confirmed by the Secretary of HHS when the nomination package is submitted for approval. The ACIP Secretariat reviews characteristics of potential candidates, including leadership skills, a demonstrated ability to maintain a smooth and timely processing of agenda items and discussion by ACIP members and the public during ACIP meetings, and ability to meet the other considerable demands placed on the Chair.

The ACIP Secretariat selects a voting member to serve as Vice Chair of the Committee. This is not a position formally described within ACIP charter, but this is quite often the person who will be invited to become the next Chair.

ACIP Secretariat and Steering Committee

The ACIP Secretariat is composed of CDC staff members. The ACIP Executive Secretary, or “Designated Federal Official,” (DFO) is a senior consultant to the Director of the National Center for Immunization and Respiratory Diseases (NCIRD). The DFO is responsible for the committee's overall management and compliance with FACA law.

Steering Committee members includes representatives from each of the major centers at CDC. Some Steering Committee members are affiliates of Work Groups within ACIP. The Steering Committee meets four times per year: once before each ACIP meeting (February, June, and October) to plan the meeting agenda and once in November/December to discuss the nomination of new members.

Work Groups

ACIP utilizes subgroups of the Committee, or Work Groups, to extensively review relevant published and unpublished data and develop recommendation options for presentation to the ACIP during its public meetings.

ACIP Work Groups 1) must include two or more ACIP voting members, one of whom serves as Chair; 2) must include CDC staff members; 3) should include an FDA staff member, if appropriate; and 4) may include *ex officio* members and liaison representatives. Only appointed ACIP voting members may chair a Work Group. On occasion, disease/vaccine experts who are not government employees, ACIP members, *ex officio* members or liaison representatives may be asked to serve as consultants to a Work Group. Members with a potential financial conflict of interest cannot serve on a Work Group that is dealing with a product that is the subject of the conflict. If the individual has unique expertise to the Work Group, that person may serve as a scientific consultant but should not participate in policy deliberations. Conflict of interest declarations are signed by Work Group members annually and changes should be announced during Work Group teleconferences.

Representatives of vaccine manufacturers may not serve as members of a Work Group but, at the discretion of the Chair, may be asked to make presentations to the group and answer questions. Following these presentations, non-Work Group members may be asked to leave in order to allow deliberations to be limited to members of the Work Group.

ACIP Work Groups accomplish most of their work through regular teleconferences. These teleconferences are closed meetings, and therefore ACIP Work Groups must observe certain guidelines that allow them to function exempt from FACA requirements. As FACA-exempt groups, ACIP Work Groups are not allowed to render consensus advice or recommendations directly to the Federal government. ACIP Work Group Chairs, other Work Group representatives, or the Work Groups per se are not empowered to speak on behalf of ACIP. Rather, they are utilized by ACIP to gather and organize information upon which ACIP can deliberate and act. Thus, while ACIP Work Groups can and should examine specific topics in detail and define the issues, including development of options for recommendations, the actual processes of group deliberation terminating in development of immunization recommendations must occur in the open public forum of ACIP meetings in compliance with FACA requirements. Additional information on ACIP Work Groups and their functioning is available in the ACIP Work Group Standard Operating Procedures document, which is available from the ACIP Secretariat.

ACIP Functions

Per its charter, ACIP's primary duties are:

- Advising and guiding the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. Recommendations made by ACIP are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in the *Morbidity and Mortality Weekly Report* (*MMWR*).

- Providing advice regarding the control of diseases for which a vaccine is licensed in the U.S. The guidance will address use of vaccines and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available. The committee also may provide recommendations that address the general use of vaccines and immune globulin preparations as a class of biologic agents.
- Establishing and periodically reviewing and, as appropriate, revising the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines, in accordance with Section 1928 of the Social Security Act.

The specific functions that support these duties are detailed below.

Process for Developing Recommendations

Technical Aspects

ACIP Work Groups are formed to extensively review relevant published and unpublished data and develop recommendation options for presentation to the ACIP during its public meetings. Additional information on ACIP Work Groups and their functioning is available in the ACIP Work Group Standard Operating Procedures document, which is available from the ACIP Secretariat.

Work Group are formed when updates to existing recommendations are anticipated based on availability of new data (regarding safety, effectiveness, and/or programmatic issues, e.g., vaccine administration or storage), or licensure of a new vaccine or new indications for existing vaccines are anticipated. In general, Work Groups should begin reviewing data 12-18 months prior to a potential decision on licensure; the length of time required for the Work Group to review data in anticipation of vaccine licensure will depend upon the complexity of the topic and the amount of available data existing. Immunoglobulin therapies and/or antimicrobial agents may be considered by ACIP in relation to control of a disease for which there is a vaccine available or under consideration.

Active Work Groups review recommendations regularly. For vaccines for which there is not a Work Group, the recommendations should be reviewed on a regular basis, at least every 7 years, and either revised, renewed, or retired with a vote by ACIP. A Work Group may or may not be established for this review, depending on whether minor or major changes to the recommendations are needed. However, a summary of any minor changes to the recommendations is presented to ACIP and voted on and published in the *MMWR*. The adult schedule, child and adolescent schedule, and influenza recommendations are published in the *MMWR* annually.

All Work Group findings generally are presented to ACIP in an open meeting, and this information is then deliberated. ACIP Work Groups are used as a resource for gathering, analyzing, and preparing information for the Committee that will discuss and deliberate on the information presented.

Developing the Recommendations

Recommendations are subject to extensive review by ACIP members, staff of the CDC and FDA, outside expert consultants, and vaccine manufacturers.

CDC vaccine recommendations are developed using an explicit evidence-based method based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. Key factors considered in development of recommendations include the balance of benefits and harms, type or quality of evidence, values and preferences of the people affected, implementation issues (excluding issues around payment and program costs) and health economic analyses. More information about GRADE can be found in the ACIP's GRADE handbook (https://www.cdc.gov/vaccines/acip/recs/grade/downloads/handbook.pdf).

Most issues that ACIP will vote upon require a GRADE evaluation of the evidence. However, a "when to GRADE" algorithm is currently under development and once it is finalized a link will be added here. A summary of the GRADE evidence should be included in the MMWR Policy Note, and the GRADE evidence tables are published on the ACIP website (https://www.cdc.gov/vaccines/acip/recs/grade/table-refs.html). If it is determined that a GRADE evaluation is not needed, the rationale for why GRADE is not being done will be clearly documented. The ACIP Secretariat is available to assist with questions about GRADE.

Additionally, the ACIP is currently evaluating adoption of an evidence to recommendations framework. Information about the framework will be added here when available.

The ACIP also provides guidance for the development of health economics studies (https://www.cdc.gov/vaccines/acip/committee/guidance/economic-studies.html). These procedures should be followed for economic analyses to be presented to the ACIP to ensure that economic data presented to the ACIP and its Work Groups are uniform in presentation, understandable, and of the highest quality.

Work Groups review all of the relevant published and unpublished data, including GRADE and economic analyses and implementation considerations. Additionally, Work Groups should seek additional data that may have been overlooked; make corrections in data content, evaluate appropriateness of the interpretation of data, and critique and challenge expert opinions. Areas in need of additional research or data should be clearly identified in presentations to the full ACIP, and each statement should include a specific delineation of data gaps.

During ACIP's decision making process the importance of the economic analyses and implementation considerations must be balanced, while also ensuring that the recommendations remain focused on the evidence base. Additionally, public comments are solicited during the Committee meetings and are considered during the decision making process.

Program staff compile and organize comments received and discuss them with the appropriate Work Group while redrafting recommendations. The Chair of the Work Group is responsible for the final review of the draft recommendations submitted for deliberation and approval by the full voting Committee.

Documents and data which will be discussed at the meeting must be disseminated to the Committee in a timely manner for the members to have the time to review the information and prepare for productive discussions. It is the responsibility of the presenters/authors to meet the timelines set by the ACIP Secretariat. These timelines are generally set ten weeks in advance of the meeting. Materials are sent electronically to the Committee members via email or the ACIP SharePoint site fourteen days prior to the meeting dates.

Meetings

Regularly scheduled meetings are held three times a year, at the call of the Executive Secretary. Meeting dates are announced 6-12 months in advance. Meeting dates and the location of the meetings are posted on ACIP's home page shortly after the dates and location are selected. At least 60 days prior to the meeting, the meeting date, items to be discussed, and location are published in the *Federal Register*. Meetings traditionally are held in Atlanta, Georgia. All regular meetings are live webcast, with instructions for accessing the webcast available on ACIP website before the meeting. Except as noted otherwise in these policies and procedures, the Chair will use Roberts Rules of Order (Eleventh Edition) as a guide when conducting Committee meetings.

In exceptional circumstances, the Director of CDC may call an emergency meeting of ACIP without prior notice, or with less than the usual 60-day notice in the *Federal Register*. If the notice cannot be published at least 60 days prior to the meeting, the *Federal Register* announcement will include the reasons for providing less than 60 days' notice, as provided under GSA regulations at 41 CFR § 102-3.150(b). If exigent circumstances make publication of the *Federal Register* notice prior to the meeting impossible, the notice shall be published in the *Federal Register* as soon as possible after the meeting. In addition, under such circumstances, the agency shall utilize other appropriate mechanisms for providing notice of the meeting prior to its occurrence.

ACIP meetings are generally open to the public for their entire duration. However, there are or may be occasions when the nature of the information is such that a closed meeting is required. Examples might include discussions of proprietary information, information related to national security interests, or information related to personnel action within CDC. Participants in closed sessions may be required to sign pledges of nondisclosure. All provisions of the Federal Advisory Committee Act and Government in the Sunshine Act regarding closed sessions will be followed.

Selection of Topics

Potential topics for ACIP consideration can be suggested by anyone, but are most often proposed by CDC program staff, FDA program staff, ACIP members, and vaccine manufacturers.

Approximately ten weeks prior to an upcoming meeting, a memorandum requesting potential agenda items is sent to ACIP voting members, CDC and FDA staff. The person suggesting an agenda item is asked to specify the topic to be on the agenda, issues of concern, and specific questions to be addressed by ACIP. Agenda items are accepted for presentation by the Steering Committee. The Executive Secretary has the authority to approve, disapprove, or hold over to another meeting any agenda item submitted for the agenda.

Voting

The Committee shall not take a vote unless a quorum of at least 13 voting members is present. Whenever eight or more members are not eligible to vote, the Executive Secretary or his or her designee shall have the authority to temporarily designate the *ex officio* members as voting members. A majority vote is accepted by the committee. In the case of a tie vote, the Chair's vote determines the final result.

Ex officio members are expected to announce any conflicts of interest prior to any voting to determine if they can vote.

ACIP is charged with providing advice and guidance regarding the use of vaccines and related agents (e.g., immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available) for the civilian population of the United States. Upon the licensure of any vaccine

or any new indication for a vaccine, the committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting. If the committee does not make a recommendation at the committee's first regularly scheduled meeting, the committee shall provide an update on the status of such committee's review.

ACIP should vote to make new recommendations when:

- There are no existing recommendations (previously not-vaccine preventable)
- The vaccine product uses a novel adjuvant
- The vaccine protects against different, or additional, serotypes, serogroups, etc.
- The age indication, number and/or schedule of doses, or population under consideration differs from previous ACIP recommendations

ACIP does not need to vote on language for clinical guidance, but they can review CDC developed clinical guidance.

The Committee shall not vote to recommend a vaccine prior to its licensure by the FDA, except where extraordinary circumstances exist that require potential use of a vaccine under an Investigational New Drug application/Emergency Use Authorization. The Chair may ask members for their individual opinions on vaccine recommendations prior to licensure in order to gain a sense of the Committee's thinking to provide program staff and Work Group members with direction in developing draft recommendations.

All ACIP recommendations that are approved by the CDC Director are considered CDC policy once published in the *Morbidity and Mortality Weekly Report*.

Public Comment

ACIP holds open discussions and reserves meeting time for public comment, which is welcomed as an essential aspect of the Committee's deliberations. Public comment is specifically invited on matters related to the ACIP's roles under the Vaccines for Children Program and the Affordable Care Act. In addition, public comments can be made on any topic relevant to the ACIP's charge as listed in the committee's Charter.

Oral Public Comment Procedures

Each ACIP meeting will include at least 60 minutes of time for in-person oral public comment, as needed. The oral public comment period will occur before any scheduled votes. Each speaker will be allotted 3 minutes to present. Each speaker may only speak once per meeting unless invited by the ACIP Chair.

Priority will be given to individuals who submit a request to make an oral public comment before the meeting and according to the procedures and deadlines in the Federal Register Notice announcing the ACIP meeting and on the ACIP meeting information website.

CDC will assign each individual who submitted a request to make an oral public comment a unique identifier number with no personally identifying information. After the deadline for submitting requests for oral public comment has passed, the list of unique identifiers will be provided to the Deputy ACIP Executive Secretary, who will use a Microsoft Excel formula to randomize the list. The randomized list will then be used to determine the order of speakers.

If more people request to make an oral public comment than can be reasonably accommodated during the allotted public comment period at an ACIP meeting, CDC will determine the number of speakers that can be reasonably accommodated in the designated oral public comment period and invite that number of speakers to comment. CDC will use a lottery system and allot time to speakers in the same order they appear in the randomized list. CDC will not give preference to any individuals, organizations, or interests. For example, if CDC determines that 20 speakers can be reasonably accommodated during the oral public comment session, the first 20 individuals on the randomized list will be allotted time to speak, while the names after the first 20 will not be allotted a time for oral public comment at that meeting. Any member of the public may still submit a written comment according to the procedures described below.

CDC will send email notification to individuals who have been allotted a time to provide an oral public comment at an ACIP meeting. Individuals who have been allotted a time must visit the CDC information desk at the meeting and sign in. If an individual who has been allotted time to provide an oral public comment at an ACIP meeting is unable to speak at the meeting, CDC may allow another person to provide the oral public comment on the individual's behalf. CDC will provide the procedures for this substitution, if applicable, in the email notification to individuals when they are allotted a time to provide an oral public comment.

On-site, in-person registration for oral public comment at the meeting will only be available if there is time remaining in the oral public comment session after all individuals who were allotted time pursuant to a request to make an oral comment before the meeting have had an opportunity to speak. There is no guarantee there will be an opportunity for on-site, in-person registration for oral public comment, and all individuals interested in making an oral public comment are strongly encouraged to submit a request in advance of the meeting according to the instructions in the Federal Register Notice and the ACIP meeting website.

The ACIP Chair or DFO will announce at the beginning of the meeting if on-site, in-person registration will be available based on the number of speakers allotted to speak during the oral public comment period. If on-site, in-person registration is available, individuals must request an opportunity to speak according to the instructions provided by the ACIP Chair or DFO at the beginning of the meeting. CDC will determine the order of speakers according to the randomization process described above. If more individuals request an opportunity to speak than there is available time, CDC will conduct a lottery according to the process above.

In addition to the procedures above, the ACIP Chair has discretion to invite individuals to make an oral public comment outside of the designated comment period when relevant to the deliberations of the ACIP.

Written Public Comment Procedures

Any member of the public can submit a written public comment to ACIP. Written comments will be accepted up to 48 hours following the end of an ACIP meeting. Comments must be submitted using the Federal eRulemaking Portal: http://www.regulations.gov using the docket number for the ACIP meeting provided in the Federal Register Notice announcing the ACIP meeting and according to the instructions on regulations.gov. All relevant comments received will be posted without change to http://regulations.gov, including any personal information provided. Comments submitted by 72 hours before the meeting will be made available to ACIP members before the meeting.

Rules of Conduct for ACIP Meetings

- An interested person who wishes to make an oral public comment during an ACIP meeting should submit a request with CDC before the meeting according to the instructions in the Federal Register Notice. Those who have not submitted a request before the meeting will only have an opportunity to speak as time permits or at the discretion of the Chair.
- Audience members may not present comments or questions to the Committee unless recognized by the Chair.
- Attendees may be subject to security screening, such as presenting identification, passing through metal detectors, and inspection of briefcases, packages, and so on.
- Attendees at the meeting are asked to maintain order and not display behavior that is disruptive to the meeting.
- The ACIP Chair or Designated Federal Officer will note on the record any disruptive behavior and will ask the person to cease the behavior or else leave the meeting room.
- Attendees are asked not to approach the ACIP table area before, during, or after the meeting without permission from the Designated Federal Officer/Executive Secretary.

Internal Decision Memos

After ACIP recommendations have been submitted to the CDC Immediate Office of the Director (IOD), the CDC Director may adopt or reject the recommendations. The DFO prepares an internal decision memo addressed to the CDC Director and obtains the necessary CIO approvals. Following these approvals, the DFO then submits this decision memo to the CDC Director, on committee stationery, in a memo signed by ACIP Chair. ACIP Recommendations should not be posted by CDC, even as "provisional recommendations," until the CDC Director approves adoption of these recommendations. If the CDC Director adopts the recommendation(s), the decision is documented on the internal decision memo.

If the CDC Director disagrees with one or more of ACIP recommendations, the decision is documented on the internal decision memo. The DFO works with CIO leadership to draft a memo for ACIP to address the Director's concerns. The Secretariat will obtain any OD clearances of the draft memo as well as the CDC Director's approval. If ACIP concurs with the CDC Director and issues modified recommendations, the Secretariat proceeds with CDC adopted recommendations (see above – Internal Decision Memo is approved). If ACIP does not modify its recommendations, a second internal decision memo is created to brief the Director on the committee's recommendations. If the Director still disagrees with ACIP recommendations, the Secretariat, with assistance from the appropriate CIOs, drafts and publishes a Federal Register Notice with opportunity for 30 days public comment that articulates the Director's views and proposed decision.

Publication of Recommendations

New and revised recommendations, once approved by the CDC Director, are published in the *MMWR* as a policy note. Comprehensive updates to ACIP recommendations, usually summarizing multiple ACIP recommendations that have been published over a period, are published in the *MMWR* as Recommendations and Reports.

Implementation and Evaluation of the Recommendations

Implementation and evaluation of the impact of the recommendations is the responsibility of the relevant CDC program not ACIP. However, CDC programs will periodically report information relevant to these activities to ACIP and others who may be involved in implementing the recommendation (e.g., managed care, private practitioners).

Electronic Recording by Public Media

The Federal Advisory Committee Act states that advisory committee meetings be open to the public to the extent allowed by law and physical environment. The Chair and the Executive Secretary have the authority to regulate all aspects of the meetings, including electronic coverage. To ensure the meeting is conducted in a fair and expeditious manner, the Chair may restrict or deny use of electronic recording equipment. Any member finding lights or recording equipment disruptive to the conduct of business at the meeting should inform the Chair or Executive Secretary. Factors to guide the Chair in this determination include the potential for significant disruption, prejudicial impact on the meeting, fairness, and impairment of a participant's ability to make a presentation or participate freely in discussion.

ACIP Recommendations for the Vaccines for Children (VFC) Program

ACIP recommendations for the VFC Program are developed and voted upon in a separate process, distinct from ACIP recommendations, after vaccines are licensed. This process is based upon the unique statutory authority for the VFC program established by the Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. §1396s). This legislation gave ACIP the responsibility and authority to determine the vaccines, number of doses, schedule and contraindications for the VFC Program.

Consistency between ACIP recommendations and VFC resolutions is a high priority. Routine recommendations and recommendations for individual clinical-decision making are included in VFC resolutions. In some situations, usually for ease of implementation, the VFC resolution can be broader than ACIP recommendation.

For each vaccine considered for inclusion in the VFC program, written resolutions on the vaccine, schedule, dose, contraindications, and other issues relevant to appropriate uses of vaccines are reviewed by the Committee and are adopted or rejected through votes by voting ACIP members. A record of issues voted on is maintained at CDC by ACIP Executive Secretary, and the requirements of approved VFC resolutions are communicated to VFC providers through the state immunization programs.

Member Roles and Responsibilities

General Member Responsibilities

Attendance at Meetings

At public meetings of ACIP, the 15 voting members vote on vaccine recommendations. Recommendations are accepted by majority voting. Votes are recorded and the vote tally is captured in ACIP meeting minutes, which are made available to the public and posted on ACIP website. The committee is updated regularly following implementation of new vaccine recommendations on pertinent data such as post-licensure safety monitoring, disease surveillance and outbreaks, and coverage.

ACIP meeting dates are published approximately six months to one year in advance. Except in the event of an emergency, members of ACIP assume the responsibility of attending all meetings. At the discretion of the

Executive Secretary, a member may be linked to a committee meeting by telephone or video conference, in which case his or her presence shall count toward the quorum. When a member does not attend a meeting or attends a portion of a meeting, the member is provided background material on the issues discussed, and is expected to be prepared to fully participate in the next meeting. If a member finds it difficult to attend meetings, he/she has the responsibility to resign from the Committee. This will allow for a new member to be appointed to carry out the term. Failure by a member to actively participate in the work of the committee, including through regular attendance at ACIP meetings, may result in a request by ACIP Executive Secretary to the Secretary of Health and Human Services to declare the position vacant with replacement of the affected member.

ACIP-Related Contacts

ACIP members may be solicited to participate in consultations or surveys on vaccine issues that are addressed by ACIP. ACIP members should not participate in such consultations or surveys if they are requested to participate because of their ACIP membership status.

The Department's Standards of Conduct prohibit "speaking" on matters related to an ACIP member's official duties outside Committee or Work Group meetings. ACIP members are prohibited from receiving compensation for any speech or publication in which the purpose is to report on the member's work on ACIP. Voting members should be concerned with, and should report to the Executive Secretary, any solicitation of information about the Committee's activities by persons not officially affiliated with the Committee.

Media Interaction

As a federal agency, CDC's advisory committee meetings generally are open to the public and the media. Therefore, Committee members may be approached by the media for an unscheduled interview. Members are not obligated to give an interview to the press either at the time they are approached or at a later time. Members are free to give interviews and express their opinions, or the views of their employer, professional organization, etc., but should have CDC approval to speak as an ACIP member on ACIP matters. CDC offers the following guidance to members who receive CDC authorization to conduct an interview:

- ACIP members may choose to do media interviews with other ACIP members or CDC staff present and participating.
- Media inquiries or requests for interviews may be referred to the CDC Office of Health Communications' representative.
- To avoid the appearance of bias, ACIP members shall not speak to the media about what they believe to be a likely outcome on an ACIP vote, prior to that vote being finalized.
- Members may discuss ACIP public meetings and their personal views, but must not disclose any proprietary information.
- Members are to be objective regarding issues brought before the Committee and should be aware that any strong public statements on Committee matters prior to a Committee vote could affect their future participation in related meetings because of the appearance of bias.
- Members should not speak to the press as representatives of either the Committee or the CDC, unless the agency designates a member to speak for the Committee (e.g., the Chair).

- Only the topic of discussion should be made public from closed portions of Committee meetings. Prior to discussing any matter discussed in a closed session, the member should consult with the Executive Secretary or a knowledgeable CDC staff member.

Committee Correspondence

Any correspondence (letter, fax, e-mail, etc.) should be routed to the Committee Management Specialist for ACIP who then consults with the Executive Secretary to determine who the most appropriate respondent is. In some cases, the Chair of ACIP is the appropriate person; in other cases, it may be the Executive Secretary or other CDC official or it may be the Chair of a Work Group. However, no member should reply to official correspondence without consulting the Executive Secretary. The only exception to this rule is that all members are free to respond to questions about established points of fact (e.g., meeting dates, citations for ACIP recommendations, etc.).

Responsibilities Specific to Member Roles

Chair

- Presides at all committee meetings and ensures that the agenda is adhered to as closely as possible. If it is necessary for the Chair to leave the meeting due to a conflict of interest, the Chair shall appoint the DFO, the Executive Secretary, or another committee member to preside. This includes those meetings conducted in person at the CDC as well as those special meetings that are called on an *ad hoc* basis and conducted via teleconference.
- Screens each voting ACIP member for conflicts of interest relevant to that vote when a vote is to be taken.
- Ensures that all rules of order and conduct are maintained during each session of an ACIP meeting. When a committee member(s) is disqualified from participation in committee discussions, the Chair ensures that the disqualified member does not participate and/or physically leaves the meeting room. In addition, the Chair ensures that the minutes and transcript clearly indicate that the member did not participate and/or was not present during the discussion.
- Calls on individuals for opinions and comments and terminates any discussion that is felt to be unnecessary.
- Calls for a motion to be made and to be seconded when voting is required; calls for a vote when the motion has been made and seconded.
- Calls for and controls public participation during the open portion of a meeting.
- Certifies to the accuracy of the minutes of each committee meeting prior to their distribution.
- With ACIP Secretariat, determines the need for establishment of new Work Groups and disbanding of Work Groups when a Work Group has completed its tasks.
- Leads the administrative meetings that are conducted at each ACIP meeting, which include as participants the voting ACIP members and selected CDC staff members. With ACIP Secretariat, develops the agenda for ACIP administrative meetings.
- With ACIP Steering Committee, assists in the development of the draft agenda for each ACIP meeting.
- As required, meets with ACIP Secretariat between ACIP meetings to discuss topics pertinent to ACIP (for example, need for a new Work Group; emerging issues such as interruptions in vaccine supply, development of influenza antiviral resistance, need to call an emergency ACIP meeting, new ACIP initiatives, agenda for ACIP administrative meeting, etc.). Such meetings generally are conducted via

teleconference and are generally attended by ACIP Chair, Vice Chair and ACIP Secretariat and others as needed.

- Represents ACIP at key meetings of other Federal Advisory Committees. The Chair may designate an alternate to attend a meeting on his/her behalf, usually ACIP Vice Chair; if the Vice Chair is unavailable, the Chair may request that another voting ACIP member attend on his/her behalf. Participation in such meetings is generally funded by ACIP/ CDC.

Vice Chair

- ACIP Chair may call upon ACIP vice Chair to assist with any of the Chair's roles and responsibilities, as required.
- In particular, the Chair and the Vice Chair may wish to divide responsibility for attendance at ACIP-related meetings (such as other Federal Advisory Committee meetings) that occur throughout the year.

Voting Members (including Chair and Vice Chair)

The Chair and members of the Committee play a critical role in ensuring the Committee's continued standing as a nationally and internationally recognized leading body in the field of immunization. ACIP members are expected to observe the highest standards of impartiality, integrity and objectivity in their deliberations, and that their recommendations should be driven by available scientific evidence. Members of ACIP will:

- Be committed to continued development and improvement in this important area of public health.
- Bring relevant experience to the Committee.
- Contribute to the provision of high quality and considered public health advice to the CDC and DHHS.
- Be expected to make a full and considered contribution to the work of the Committee and to contribute fully to the debate and to the decision-making processes.
- Provide expert guidance when an issue that falls within their particular area of expertise is under discussion.
- Contribute to the debate in the capacity of a well-informed health professional when the issue does not fall within their expertise.
- Take into account the need for and impact of vaccines, the quality and safety of vaccines and strategies to ensure that the greatest benefit can be obtained from the most appropriate use of vaccines.
- Be prepared to respond quickly to interaction by e-mail.
- Be prepared, as requested by the Secretariat, to attend and contribute to the work of one or more of ACIP work groups, which report to ACIP, and to attend occasional meetings of other Federal Advisory Committees on vaccines for which representation of ACIP would be needed.
- Be committed to declare all relevant interests. Any reported interest that could be perceived as a potential conflict of interest will be disclosed during public ACIP meetings and in written meeting minutes, which are posted on ACIP website.

All members serve in their personal capacity and should refrain from promoting the policies and views and products of the organization/institution for which they work.

Conflicts of Interest when Participating as a Member

Upon appointment, each voting member is required to file an Office of Government Ethics 450 form (OGE450 http://www.oge.gov/Forms-Library/OGE-Form-450--Confidential-Financial-Disclosure-Report/) and a

Confidential Financial Disclosure Report, which is reviewed by ACIP Secretariat, the Federal Advisory Committee Management Branch and the Office of General Counsel at CDC. CDC will individually evaluate and consider for waiver the related financial interests of each ACIP member in accordance with the OGE regulations at 5 CFR Parts 2635 and 2640, in particular to determine whether the need for the individual's services outweighs the potential for conflicts of interest created by the financial interests involved. Taking into consideration the nature of ACIP, the types of expertise necessary to accomplish its purpose, the various ways in which vaccine expertise is developed, and the integrity of the advisory committee process, CDC will generally consider issuance of waivers in specific situations as detailed in the Appendix.

Confidential Financial Disclosure must be updated annually during a member's term. At every ACIP meeting, the Chair calls for conflict of interest disclosure from each voting member at the opening of the meeting. Additionally, each voting member must declare any conflict of interest related to a particular vote prior to the vote being taken by ACIP. Any actual or perceived conflict of interests will be explored fully by the Secretariat, CDC's Federal Advisory Committee Management Branch, and CDC legal counsel if necessary. Members with declared interests will be asked to recuse themselves from participating in the discussion and decision making of the issues relating to that interest. A member who has any doubt as to whether he/she has an interest that should be declared, or whether he/she should take part in the proceedings, should ask the Secretariat for guidance.

As detailed below and in the Appendix, ACIP members will have consented to the following requirements as a condition of membership.

- No member, his or her spouse, or a member of his or her immediate family can be directly employed by a vaccine manufacturer or its parent company.
- Members cannot hold stock in any vaccine manufacturer or its parent company in excess of the OGE *de minimus* amounts. Members also agree that they, their spouse and minor children will not purchase such stock during their tenure on the committee.
- Members cannot be holders of or otherwise be entitled to royalties or other compensation for a patent on a vaccine product or process, immunologic agent, adjunct or preservative that can be used for a vaccine that may come before ACIP during the anticipated term of appointment under consideration.
- Members agree to resign any advisory or consulting roles, whether paid or unpaid, to a vaccine manufacturer (except participation in clinical trials or service on data monitoring boards) and to forego such consultation or membership on any vaccine manufacturer advisory committees (except participation in clinical trials or service on data monitoring boards), during his/her tenure on ACIP.
- Members forego solicitation or acceptance of funds from vaccine manufacturers on behalf of themselves or others.
- During their tenure on ACIP, members do not serve as a paid litigation consultant or expert witness in litigation involving a vaccine manufacturer.
- Members do not accept honoraria or travel reimbursement with a funding source from a vaccine manufacturer for attendance at scientific meetings, with the exception that they may receive travel reimbursement for CME presentations where the source of funding is an unrestricted grant to the CME provider by a vaccine manufacturer.

Membership Policies and Procedures

Voting Members

Appointment of ACIP members is made by the Secretary of Health and Human Services upon the proposal of the Steering Committee, but the Secretary may select members other than those recommended by the Steering Committee. Members of ACIP are appointed to serve for a term of four years, which in general is not renewable.

Appointments and Tenure

Members will be appointed for a term of four years, which typically begins on July 1 in the year of appointment. In general, a member's term may not be extended beyond four years, and appointment to a second term is not allowed. In cases when a new round of appointees has not been approved by the Secretary to begin their terms, existing ACIP members may be asked to extend their terms until their replacements have been appointed.

The Chair shall be appointed for a term of three years. The Chair is selected and appointed by the Secretary, HHS from among voting ACIP members who have had at least two years of experience serving on ACIP and have demonstrated the ability both to lead the work of similar bodies and to work effectively with CDC.

New Members

Membership Qualifications

ACIP members are acknowledged experts with an outstanding record of achievement in their own fields and an understanding of the immunization issues covered by ACIP. They have a responsibility to provide CDC with high quality, well-considered advice and recommendations on matters described in ACIP Charter.

Solicitation for Nominees

Each year, suggestions for members are sought from a variety of sources, including professional societies, current and former ACIP members, vaccine manufacturers, and the general public. During the year, suggestions for membership to the Committee are received from various sources. These submissions are compiled for consideration along with those received from the solicitation. When openings for membership occur, a solicitation for nominations will be posted on ACIP home page and published in the *Federal Register*.

Selection of Nominees

A listing of individuals suggested for nomination to the Committee is prepared and forwarded to the Executive Secretary, ACIP, and Steering Committee members. These individuals discuss the qualifications of the candidates and the expertise needed on the Committee to develop a slate of potential nominees. Selected candidates are then contacted to determine their willingness to serve on the Committee and to adhere to limitations in their financial relationships with vaccine manufacturers as described in this document.

All appointed ACIP members become Special Government Employees, subject to the federal laws that prohibit participation in matters in which they have a financial interest. Candidates must agree to comply with ACIP policies and procedures. With concurrence from the candidates, the slate of nominees is submitted to the Director of CDC for concurrence and authorization to prepare the nomination package.

The Director of CDC approves the final nomination package, which is then submitted to the HHS Secretary. The Secretary is responsible for appointing the member(s) to the Committee, who may or may not be those nominated by CDC. If an appointment is confirmed by the Secretary, the new member serves for a term of up to four years. A member who is unable to fulfill the full term on the Committee may resign by submitting a letter of

resignation to the Executive Secretary. If a member resigns, a new member is appointed to fill the remainder of the unexpired term.

Once the name of an individual is submitted as a possible nominee to the Committee, the name and information received on the candidate is held and may reconsidered in a future year if that person expresses an interest in continuing to be considered.

Notification to Applicants

Once the nomination package is submitted, both applicants who have and have not been put forward are notified. After approval, the Secretary of HHS sends letters of congratulation to those candidates accepted for service on ACIP. The respondents return an attached form to indicate acceptance (or non-acceptance) of appointment.

Once selection is finalized, candidates who were not selected will be sent an official letter. Candidates not selected may be reconsidered for the following year.

Consideration for Nomination: Financial Conflicts of Interest

In order to achieve the highest quality comprehensive recommendations for administration of vaccines, it is critical that individuals chosen for membership on ACIP have significant vaccine and immunization expertise, including crosscutting knowledge and experience in the various aspects of the immunization field. Some expertise important to the committee can only be developed through working relationships with vaccine manufacturers, which are in a position to be financially affected by many of the recommendations of ACIP.

Federal law (18 U.S.C. §208) prohibits federal executive branch employees, including Special Government Employees (e.g., members of Federal Advisory Committees such as ACIP), from participating in matters in which, to their knowledge, they, their spouse, minor child, or organization has a financial interest. CDC is sensitive to concerns about potential conflicts of interest by members serving on ACIP, particularly given the substantial financial implications some ACIP recommendations may have for vaccine manufacturers. Therefore, to assure the integrity of the committee, CDC has taken steps to assure that there is not only technical compliance with the ethics statutes and regulations regarding financial conflicts and the appearance of financial conflicts of interest, but also that more general concerns regarding the potential for the appearance of a conflict are addressed, or avoided altogether, through both pre- and post-appointment considerations. CDC has concluded that particular interests create conflicts, or perceptions of conflicts, which either contribute little or nothing to the ongoing level of expertise required on the committee, or create an appearance of such a strong interest in the success or failure of the products of a vaccine manufacturer, that such interests should disqualify an individual from membership on the committee. These include:

- A person will be not be considered for membership if they, their spouse, or a member of their immediate family is directly employed by a vaccine manufacturer or its parent company.
- Persons who hold stock in any vaccine manufacturer or its parent company in excess of the Office of Government Ethics (OGE) *de minimus* amounts will not be considered for nomination unless they agree to divest themselves of such stock before their term of office begins and all nominees must agree that they, their spouse and minor children will not purchase such stock during their tenure on the committee.

- A person will be not be considered for membership if that person is a holder of, or otherwise is entitled to royalties or other compensation for, a patent on a vaccine product or process, immunologic agent, adjunct or preservative that can be used for a vaccine that may come before ACIP during the anticipated term of appointment under consideration.
- To be considered for appointment to ACIP, a potential nominee must agree to resign any advisory or consulting roles, whether paid or unpaid, to a vaccine manufacturer (except participation in clinical trials or service on data monitoring boards) and to forego such consultation or membership on any vaccine manufacturer advisory committees (except participation in clinical trials or service on data monitoring boards), during his/her tenure on ACIP.
- Except as allowed under the previous bullet, potential nominees must agree that during their tenure on ACIP they will forego solicitation or acceptance of funds from vaccine manufacturers on behalf of themselves or others (e.g., to support educational activities of their Department or an organization of which they are a member, officer or employee).
- Potential nominees must agree that during their tenure on ACIP they will not serve as a paid litigation consultant or expert witness in litigation involving a vaccine manufacturer.
- Potential nominees must agree that during their tenure on ACIP they will not accept honoraria or travel reimbursement with a funding source from a vaccine manufacturer for attendance at scientific meetings, with the exception that they may receive travel reimbursement for CME presentations where the source of funding is an unrestricted grant to the CME provider by a vaccine manufacturer.

Orientation and Education

Orientation for new members is provided to enable members to fully understand the work and functioning of ACIP, including participation in ACIP work groups. This is typically offered as a two-hour teleconference/webinar within one month of appointment of new members. The Secretariat will further arrange briefing and meetings with CDC staff and any other training in order to facilitate the full engagement of new members in the work of ACIP. From time to time, ACIP Secretariat arranges educational sessions on topics such as the role of health economics in development of ACIP recommendations, immunization safety monitoring and procedures used in development of evidence-based recommendations. These sessions are sometimes held at the CDC on the day before an ACIP meeting.

Table. ACIP Membership (as of October 2017)

Group	n	Description of members
Voting members	14	Subject matter experts in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and/or preventive medicine
	1	Consumer representative who provides perspectives on the social and community aspects of vaccination.
Ex officio members (non-voting)	8	Individuals in the roles listed below or their designees. • Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration • Deputy Director for Scientific Activities, Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense • Under Secretary for Health, Department of Veterans Affairs • Director, Center for Biologics Evaluation and Research, Food and Drug Administration • Director, Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services • Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health • Director, Indian Health Service • Director, National Vaccine Program Office, HHS
Liaison representatives from professional organizations (non-voting)	31	Participating organizations: • American Academy of Family Physicians • American Academy of Pediatrics • American Academy of Physician Assistants • American College Health Association • American College of Nurse Midwives • American College of Obstetricians and Gynecologists • American College of Physicians • American Geriatrics Society; • America's Health Insurance Plans • American Medical Association • American Nurses Association • American Osteopathic Association • American Pharmacists Association • Association of Immunization Managers • Association for Prevention Teaching and Research • Association of State and Territorial Health Officials • Biotechnology Industry Organization • Council of State and Territorial Epidemiologists • Canadian National Advisory Committee on Immunization • Infectious Diseases Society of America • National Association of County and City Health Official • National Association for Pediatric Nurse Practitioners • National Foundation for Infectious Diseases • National Immunization Council and Child Health Program, Mexico

		• National Medical Association • National Vaccine Advisory Committee • Pediatric Infectious Diseases Society • Pharmaceutical Research Manufacturers of America • Society for Adolescent Health and Medicine • Society for Healthcare Epidemiology of America

Appendix. Member Conflicts of Interest and Financial Interests

ACIP members must file Office of Government Ethics (OGE) Confidential Financial Disclosure Reports, Form 450, as required by OGE regulations and the CDC policy and the Financial Disclosure for Federal Advisory Committee Members Appointed as Special Government Employees. CDC will individually evaluate and consider for waiver the related financial interests of each ACIP member in accordance with the OGE regulations at 5 CFR Parts 2635 and 2640, in particular to determine whether the need for the individual's services outweighs the potential for conflicts of interest created by the financial interests involved. Taking into consideration the nature of ACIP, the types of expertise necessary to accomplish its purpose, the various ways in which vaccine expertise is developed, and the integrity of the advisory committee process, CDC will generally consider issuance of waivers as follows:

1. **Limited Waivers.** Where conflicts exist, only limited 208(b)(3) waivers will be considered, except as noted in number 6, below.

2. **Scope of Limited Waivers.** Limited waivers will generally allow members to fully participate in committee discussions related to waived interests, with the condition that they will be prohibited from voting on such matters (except in the case of *de minimus* interests which do not disqualify a member from voting). In addition, members will be prohibited from serving as chairs of subcommittees or Work Groups considering issues where conflicts exist.

3. **Clinical Trials.** A member who is serving as a principle investigator or as a member of a data monitoring board on manufacturer-sponsored research will be considered for issuance of a limited 208(b)(3) waiver to serve as a consultant to present to ACIP on matters related to this manufacturers' vaccine, but cannot participate in deliberations or vote on such issues. The member may be granted a waiver as described in number 2, above, for issues related to other vaccines produced or marketed by that manufacturer.

4. **Public Disclosure.** In order to assure that their fellow committee members and the public are aware of a member's related financial interests; continued membership on the committee will be conditioned on the member's agreement to publicly disclose all vaccine-related interests and work, including participation in clinical trials, at the beginning of each ACIP meeting.

5. **Vaccine Stocks.** As provided in section B.1.b., except as allowed under OGE regulatory exemptions for *de minimus* amounts, members must agree to not own vaccine stocks during their committee tenure. In order to avoid even the appearance of a conflict, ownership of any amount of vaccine stocks is discouraged. Therefore, ownership by the member, spouse or minor children of *de minimus* amounts of stock in any vaccine manufacturer or its parent company must be disclosed at the beginning of each ACIP meeting.

6. **Disclosure Not Required - Uncontrolled Interests.** The member's employing institution may have financial interests which provide income to the member (e.g., grant funds deposited into a common account), but which interests are outside the member's area of work. Such interests are considered outside the member's control, as are an employing institution's financial interests that do not provide income to the member. Given the lack of control, those interests, if they may be imputed to the member under 208, will generally be waived under 208(b)(3) and, if waived, are not required to be disclosed. There are no restrictions on Committee activities based on such waived interests.

7. **Tenure Commitments.** Continuing membership on the committee and issuance and maintenance of any waiver will also be conditioned on the member's fulfillment of commitments noted in section B.1 regarding interests during their tenure on the committee.