

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES: WORK GROUPS

Conflict of Interest Policy: December 2023

Advisory Committee on Immunization Practices Secretariat
Centers for Disease Control and Prevention

ACIP Work Groups (WG) serve a key scientific role in support of vaccine policy development by ACIP. In order to avoid undue influence or the appearance/perception of a conflict of interest in WG discussions, screening for potential conflicts will be conducted upon establishment of a WG and annual updates will be collected from WG members to ensure that financial or other conflicts are not present and/or have not changed. The ACIP Secretariat will assist with the collection of conflict of interest disclosures; screening of the conflict of interest declarations will be conducted by the WG Lead in conjunction with the ACIP Secretariat.

The ACIP Secretariat will consider issuance of waivers to this conflict of interest policy in limited situations. Waivers may be issued if it is determined that an individual's subject matter expertise is necessary for work group deliberations and another expert is not available who could fulfill this role. In situations where a waiver is granted, the conflict of interest (or perceived conflict of interest) should be regularly announced to the WG.

Note: The conflict of interest policy for ACIP WG members outlined here applies to vaccines or related products under the purview of each ACIP WG on which a person serves, as well as the pharmaceutical company(s) that manufactures the vaccines or related products under the purview of each ACIP WG on which a person serves.

Because WG members are most familiar with their own situations, their personal responsibilities include the following: (1) to alert the WG Lead about any possible conflict of interest that may impact perception of impartial and fair activities of WG members and (2) to identify and certify on an annual conflict of interest screening form (a) any aspect of the work of the ACIP WG where a conflict of interest exists, and (b) that there will not be, and has not been, involvement in the efforts of the WG where participation constitutes a conflict of interest.

When a possible conflict of interest is reported by a WG member, the WG Lead will consult with the ACIP Executive Secretary (and legal counsel if necessary), to determine whether the particular situation involves a conflict of interest or an appearance/perception of a conflict of interest which 1) requires that the WG member not be involved in the ACIP WG process, or 2) the potential conflict of interest must be disclosed to the WG, but participation in the ACIP WG process is allowed.

A conflict of interest exists when a participant has a financial interest in a vaccine product, related product (e.g., monoclonal antibody), or pharmaceutical company that manufactures vaccines (or related products) that may affect his/her imputed financial interests or potentially bias his/her approach to development of options for recommendations for use of that vaccine, or of a competing vaccine.

In addition, WG members who feel they might be unable to provide impartial advice on the matter at issue for any reason, or who have made public statements (written or oral) that would indicate

to an observer that you have taken a position on the products or issue under consideration should disclose this as a potential conflict of interest.

Regardless of the level of financial involvement or other conflict of interest, if the participant feels unable to provide objective advice, they must recuse themselves from the WG activities under consideration. The ACIP WG process relies on the integrity of each participant to disclose to the WG Chair or WG Lead any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal.

The following guidance and definitions will assist in determining whether a conflict of interest exists. **This guidance applies to vaccines or related products under the purview of each ACIP WG on which a person serves and the pharmaceutical company(s) that manufactures the vaccines or related products under the purview of each ACIP WG on which a person serves.** This guidance is not all-inclusive, due to the variety of possible conflicts of interest and the potential for appearance of conflicts of interest.

Situations where a conflict of interest exists and the individual should not serve as a WG member include:

1. A person or a member of their immediate family is employed directly by a vaccine/product manufacturer or its parent company. A member of the immediate family includes spouse, domestic partner, or child.
2. A person or a member of their immediate family holds stock in a vaccine/product manufacturer or its parent company in excess of the OGE *de minimus* amounts (<https://ethics.od.nih.gov/waiver>).
3. A person is a holder of, or otherwise is entitled to royalties or other compensation for, a patent (planned, issued, or pending) on a vaccine/product or process, immunologic agent, adjuvant, or preservative that can be used for a vaccine that may come before ACIP for review/discussion during the anticipated term of the concerned WG.
4. A person holds a paid advisory or consulting role with a manufacturer to perform work related to vaccines/products expected to be considered by the WG or companies that manufacture vaccines/products under the purview of the WG. A person must agree to forego such paid consultation or membership during his/her tenure on the ACIP WG (except participation in research studies or service on data monitoring boards – see below).
5. A person is a 1) principal investigator, 2) co-principal investigator, or 3) a site principal investigator for an industry sponsored clinical trial involving a vaccine or manufacturer under the purview of the WG (even when funding goes to the institution/program).
6. WG members should agree that they will not serve as a paid litigation consultant or expert witness in litigation involving a vaccine or manufacturer under the purview of the WG.

Potential conflicts of interest that should be disclosed but do not limit¹ participation of the individual on the WG include:

1. WG members are required to disclose participation in conducting research studies funded by pharmaceutical companies and service on data monitoring boards (paid or unpaid).
2. WG members should disclose any uncompensated single time participation in advisory boards, or lectures on behalf of a pharmaceutical company that occurred in the prior 6 months. Participation in these activities should cease during tenure on the WG.
3. WG members should disclose any honoraria received for continuing medical education (CME) presentations that occurred in the prior 6 months where the source of funding was an unrestricted grant to the CME provider by a vaccine manufacturer and where all CME rules and regulations are followed. Participation in these activities should cease during tenure on the WG.
4. Non-financial conflicts (e.g. uncompensated participation in vaccine development, or a researcher identified with a particular scientific perspective in a controversial area), should also be disclosed and considered prior to participation.
5. WG members should disclose any potential reasons they might be unable to provide impartial advice, or any reason that their impartiality in the matter might be questioned. In addition, public statements (written or oral) that would indicate to an observer that the WG member has taken a position on the products or issue under consideration should be disclosed.

Activities not considered a potential conflict of interest include:

1. WG members may receive travel reimbursement for continuing medical education (CME) presentations where the source of funding is an unrestricted grant to the CME provider by a vaccine manufacturer and where all CME rules and regulations are followed.
2. Discussions with pharmaceutical representatives in regards to purchasing vaccines for a clinical practice.

WG members have an ongoing obligation to bring any new information regarding potential conflict(s) of interest to the attention of the WG Lead. In addition, WG members must inform the WG Lead if they are contacted directly by a representative of a vaccine manufacturer regarding a vaccine/product under consideration by the WG on which they serve; the WG Lead will then inform the ACIP Secretariat of any such contact.

¹ Waivers may be issued by the Secretariat in consultation with the work group lead.