



AMERICAN SOCIETY of HEMATOLOGY

Helping hematologists conquer blood diseases worldwide

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Conflict of Interest

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The American Society of Hematology (ASH) is dedicated to advancing the specialty of hematology. To accomplish this mission, ASH provides support for a variety of activities in the areas of research, education, training, and advocacy. The integrity of ASH and the activities it undertakes depends on the avoidance of conflicts of interest, or even the appearance of conflicts, by the individuals involved with those activities.

ASH has adopted eight principles that underscore its commitment to managing real/perceived conflicts of interest, as well as eight policies that lay out specific ways in which the Society safeguards the integrity of the programs and activities in which its membership is engaged. This document constitutes the "ASH Conflict of Interest Policy."

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I. Principles

Principle 1: The integrity of ASH and the scientific, educational, and advocacy activities it undertakes depend on the avoidance of bias arising from conflicts of interest, or from the appearance of such conflicts, by the individuals involved with those activities. Personal financial considerations must never be allowed to cloud physicians' and scientists' decisions on care of patients, safety of drugs or devices, or proper conduct of biomedical research. Continuing medical education (CME) provided to physicians by ASH must be free of bias devolving from financial arrangements or considerations.

Principle 2: A conflict of interest exists when an individual has material interests outside of ASH that could influence or could be perceived as influencing his/her decisions, actions, or presentations. These interests, which include employment, consultancy, equity, research funding, honoraria, patents and

royalties, speakers bureau involvement, advisory committee or board of directors membership, expert testimony, and financial support from a commercial entity for the costs of travel to the ASH annual meeting, are relevant if they occurred in the past 24 months for the volunteer, partner, or spouse. Conflicts of commercial interest may involve either an agent or device as the subject in question or an agent or device that might be in competition with the subject in question.

ASH recognizes that there are varying degrees of conflict. For example, serving on a data safety monitoring board would likely present less of a conflict than serving on a board of directors or speakers bureau. All potential conflicts must be disclosed so that the audience or committee can evaluate the relevancy of the conflict.

Principle 3: The atmosphere ASH desires is one where people are comfortable asking questions relating to conflict of interest without feeling awkward or accusatorial and where recusing one's self from participation in discussions that might be perceived as constituting a conflict is the norm rather than the exception.

Principle 4: Having a member of ASH with a conflict of interest does not necessarily preclude participation in ASH activities. In fact, such external relationships may enhance the value of that member to the Society.

Principle 5: ASH subscribes to the view that research and development sponsored by the biomedical industry play an important role in biomedical research and that academic-industrial relationships have developed useful and life-saving products.

Principle 6: The mission of ASH does not include marketing of pharmaceutical or biomedical products. While opportunities do exist for purchase of space for commercial displays at the ASH annual meeting and while certain ASH publications sell advertising pages, the revenues generated are devoted to the support of the Society's mission. To this end, strong firewalls have been designed to insulate ASH from inappropriate commercial influence.

Principle 7: The ASH policies are congruent with the positions of the Accreditation Council for Continuing Medical Education (ACCME) that state: (a) commercial support for CME must be acknowledged, (b) no employees or staff consultants in the interested company can be involved in the development of the CME activities, and (c) attendees be encouraged to report on their perceptions of any possible bias.

Principle 8: The considerations of conflict of interest are relevant not only to clinical research but may extend to all phases of biomedical research, including pre-clinical research. In pre-clinical research, financial conflicts of interest are particularly apt to lead to bias if the work is "reasonably anticipated; (a) to be a component of an Investigational New Drug application (IND) submission or (b) to progress to research involving human subjects within the coming 12 months."

II. Policies

The requirements of ASH apply to all persons who:

1. Are employees of ASH;
2. Seek to make presentations at any ASH meeting or to submit material for any ASH publication; or

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3. Serve on the Executive Committee or other committees, or otherwise serve in an official service capacity on behalf of the Society.

Policy 1: Some individuals serve as expert witnesses, officers, directors, or members of scientific advisory boards of companies, participate in company-sponsored speakers' bureaus, or accept subsidies from a commercial entity for the costs of travel to the ASH annual meeting. All of these activities represent conflicts of interest.

Policy 2: ASH holds its members serving in governance positions to certain standards with regard to conflict of interest. Specifically, when an ASH member has a conflict, s/he will not:

1. Take any action on behalf of ASH concerning the subject in conflict or any issue relevant to the subject in conflict;
2. Participate in discussions on the subject without full disclosure;
3. Participate in decision-making discussions or cast a vote;
4. Imply that he/she is acting on behalf of ASH when discussing the relevant subject with third parties;
5. Fail to clarify with third parties with whom he/she deals on the relevant subject that he/she is not acting on behalf of ASH; or
6. Share confidential information, including disclosure of embargoed abstract data which would break laws relating to insider trading.

ASH prohibits the Officers (i.e. President, President-Elect, Vice President, Secretary, and Treasurer) from simultaneously serving the Society and holding an officer position with another national or international medical organization. ASH also prohibits the Officers from simultaneous service in any position on the board of organizations with significant overlap with ASH.

Policy 3: ASH has the right to take action regarding individuals who have exhibited biased behavior or action. These actions may include:

1. Requiring an individual to choose between the competing activities.
2. Prohibiting an individual from playing a decision-making role in ASH relevant to the conflict.
3. Prohibiting an individual from presenting at ASH-sponsored events.
4. Exclusion from publishing in *Blood* or other ASH publications.
5. Exclusion from participating in ASH committees.
6. Revocation of membership in ASH.

Policy 4: No donor, commercial or otherwise, can select speakers or awardees or be involved in the production of educational and/or scientific content.

Policy 5: Commercial support for CME must be acknowledged and no employees or staff consultants of the interested company can be involved in the development of the content of CME of ASH. Meeting attendees are provided with a formal opportunity to report on their perceptions of any possible bias in their review of the sessions for CME credit.

Policy 6: ASH considers certain clearly defined types of academic consulting and fees exempt from its definition of reportable financial interests, e.g., fees received for serving on grant application review groups (study sections) and fees given as honoraria by another academic institution for an academic activity, such as seminars and grand rounds.

Policy 7: Special precautions are taken to safeguard against a potential conflict of interest with regard to the Clinical Research Training Institute, which is targeted at helping trainees (fellows and junior faculty) who are early in their careers and wish to obtain the skills needed to design and conduct studies involving human subjects. More specifically, there are no corporate exhibits or handouts, no corporate contributions have been sought for funding. From time to time, speakers who work for a pharmaceutical company are included as faculty because of their knowledge of the drug development process. These individuals are chosen solely for their knowledge of the subject matter, and they do not make promotional presentations of any kind at the Clinical Research Training Institute program.

Policy 8: ASH sponsors the development of evidence-based clinical practice guidelines. Special policies intended to prevent bias from conflicts of interest apply to participants in ASH guideline development. These policies are fully described in the document “Management of Conflict of Interest in the Development of Clinical Practice Guidelines by the American Society of Hematology,” available upon request. The policies address funding of guideline development, vetting and composition of guideline development panels, evidence review, voting and recusal, approval of guidelines, and publications of disclosures. The policies are consistent with standards recommended by the Institute of Medicine and with principles described by the Council of Medical Specialty Societies.

III. Process

Education/Awareness

ASH takes seriously its commitment to preserving the scientific integrity of its programs through transparency and proper management of conflicts of interest. Over the past several years, the Society has taken a number of steps to educate its leadership and volunteers about the importance of adhering to the ASH Conflict of Interest Policy. In an effort to ensure that sensitivity to potential conflicts is intrinsic to the Society’s culture, the following measures have been implemented:

- The Nominating Committee Chair contacts potential leadership election candidates (for Officer or Councillor) to determine any conflicts of interest; agreement to resolve such conflicts and comply with all aspects of the ASH Conflict of Interest Policy relevant to individuals in governance positions is a prerequisite for inclusion on the election ballot.
- A new member orientation is held annually for incoming Executive Committee members (Officers, standing committee chairs, and editors-in-chief) which includes a detailed presentation on the ASH Conflict of Interest Policy, along with case studies to encourage discussion.
- Every committee meeting begins with a review of the ASH Conflict of Interest Policy and processes for managing conflicts during meetings.
- Any meeting speaker who declares a conflict is provided with a reminder about the ASH Conflict of Interest Policy and a copy of the ACCME Standards for Commercial Support prior to his/her presentation.
- Slides that run between sessions at the ASH annual meeting encourage audience members to report any speaker bias and to address the issue during the question-and-answer period.

Meeting Program Design

As an ACCME-accredited provider of CME, ASH fully complies with the ACCME guidelines regarding educational program design and evaluation, as well as the ACCME Standards for Commercial Support, ensuring that the program design, implementation, and evaluation processes are free from commercial influence.

- Each individual in a position to determine the content of an educational activity must disclose all relevant financial relationships that involve the receipt of wages, compensation or other remuneration for their services as an employee or consultant with any commercial interest and follow the Society's policy for managing conflicts.
- The terms, conditions, and purposes of any commercial support of the CME program are documented in a written letter of agreement between ASH and the commercial supporter. The agreement states that ASH, not the commercial supporter, makes all decisions regarding the educational content of the program, selection of speakers, and disbursement of commercial support.
- Under no circumstances may honoraria be paid directly to speakers/faculty by commercial supporters.
- Acknowledgment of corporate support is provided on the ASH website, in the printed meeting materials, and on signage on-site.
- Product promotion and product-specific advertisement of any type are prohibited in or during CME activities.
- Corporate-sponsored symposia that occur the day before the official start of the ASH annual meeting must adhere to ACCME standards for commercial support. ASH prohibits any invited annual meeting speaker from participating in a corporate program in the same year.

Administration/Disclosure of Conflicts

To facilitate the collection of information about potential conflicts, ASH utilizes an online system in which participants in ASH committees, publications, and programs enter or update information in real time about their relevant disclosures in a central database.

For publications and CME activities, relevant disclosure information is provided to the audience in conjunction with each activity. The disclosure identifies those in receipt of wages, compensation or other remuneration for their services as an employee or consultant; the disclosure will also identify those who report no relevant financial relationships.

Specifically:

- For all ASH CME meetings (including the annual meeting, ASH Meeting on Hematologic Malignancies, Highlights of ASH, and Clinical Research Training Institute), invited speaker disclosure information is provided on a slide shown during the presentation, and in the written meeting materials. For abstract presentations, the disclosure is included in the abstract itself, both in the print copy and online. Poster presentations contain a disclosure statement on the poster itself.
- In ASH publications, author disclosures are provided as part of each article or chapter and editor disclosures are provided in a prominent location.

For committee meetings and study sections, it is critical for participants to be aware of conflicts so decisions can be made without bias. Per ASH policy, when a subject comes up that presents a potential conflict, the member must state the conflict, refrain from participating in decision-making or voting on that particular issue by leaving the room. To help ensure that the policy is followed:

- Each year the committee chair designates a committee member to serve as the Conflict of Interest Compliance Officer. Prior to each committee meeting, this individual receives a report of the

declared conflicts for each committee member so that he/she can facilitate the proper management of conflicts.

- Disclosures for the five ASH Officers, editors-in-chief serving on the Executive Committee, Executive Director, and Deputy Executive Director are publicly accessible on the ASH website.
- In the case of ASH study sections, such as those that review award/grant applications, the conflicts more commonly involve institutional or personal (rather than financial) ties, although the standard process for recusal is followed.
- The annual meeting abstracts are selected through a blinded review process, and staff members monitor each conference call to ensure that proper procedures are followed.

Enforcement

A number of efforts are put in place to ensure compliance with the ASH Conflict of Interest Policy and address any violations.

- Staff members ensure there is a disclosure slide for each presentation and physically post disclosure information to any poster that does not include it.
- Session chairs are provided with disclosure information for each of the speakers in their sessions.
- Committee volunteers formally review speaker presentations for any bias or the appearance thereof.
- Staff and committee volunteers monitor each Friday Satellite Symposium (corporate-sponsored programs held the day prior to the annual meeting); sponsoring groups are required to provide ASH with summaries of attendee feedback.
- The centralized disclosure system allows staff to track and follow up with any individual who neglects to disclose; no one is allowed to participate in an ASH meeting until this is addressed.
- In the event that ASH receives a report of speaker bias or failure to disclose, a report is presented to the Executive Committee, which determines consequent action on a case-by-case basis. Such action may range from a written warning to the speaker about adherence to the ASH COI policy to prohibition from participation in future ASH events.

Questions?

Questions and comments regarding the ASH conflict of interest principles and policies can be directed to the ASH Deputy Executive Director, Matthew Gertzog at mgertzog@hematology.org.

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