



American Society of Clinical Oncology

CONFLICT OF INTEREST MANAGEMENT PROCEDURES for CLINICAL PRACTICE GUIDELINES¹

As the leading medical society for physicians involved in cancer treatment and research, the American Society of Clinical Oncology (ASCO) has an important role in helping physicians deliver quality oncology care. One of the primary ways in which ASCO fulfills this responsibility is through the development of clinical practice guidelines, technology assessments, and clinical evidence reviews. Public confidence in these guidelines depends on the cultivation of expert opinions based on the best available evidence and in a manner designed to minimize actual and perceived conflicts of interest.

For ASCO, guideline development is a multi-step process. Once drafted by a diverse panel of experts, guidelines must be approved by the Clinical Practice Guideline Committee, adopted by the Board of Directors, and peer-reviewed in accordance with rigorous standards set by the *Journal of Clinical Oncology (JCO)*. The following procedures provide strategies for managing potential conflicts of interest through each phase of guideline development.

I. Identifying Affected Companies

Commercial entities with products affected by a guideline are considered “affected companies” for purposes of conflict of interest review of ASCO guidelines. A commercial entity is an affected company if there is a reasonable likelihood of direct regulatory or commercial impact (positive or negative) on the entity as a result of care delivered in accordance with guideline recommendations. To facilitate identification of potential conflicts of interest, affected companies will generally be identified at the time of development of the guideline protocol, prior to selection of panel members, chairs or co-chairs. For guidelines already under development, affected companies will be identified before the guideline is reviewed by the Clinical Practice Guideline Committee.

Affected companies will generally be identified by an independent party who will not serve as a panel member or guideline reviewer. In some cases where identification is straightforward, an ASCO staff member from the Cancer Policy and Clinical Affairs Department may identify affected companies using criteria approved by the independent party. The list of affected companies should remain consistent throughout guideline development and adoption. If changes in the marketplace or in the focus of the guideline make revisions necessary, a modified list may be developed or reviewed by the independent party. The list of companies affected by a guideline will be made available to prospective guideline panel chairs and panel members, the Clinical Practice Guideline Committee, and the Board by the Cancer Policy and Clinical Affairs Department.

¹ The Implementation of ASCO’s Conflict of Interest Implementation to Clinical Practice Guideline Panel Co-Chairs and Expert Panel Members was originally adopted by the ASCO Board of Directors December 19, 2005. The Conflict of Interest Management Procedures for Clinical Practice Guidelines was adopted by the ASCO Board of Directors on December 3, 2007.

II. Panels

a. Disclosure

All prospective panel members, including prospective panel chairs and co-chairs, disclose financial interests and other relationships with entities that have an investment, licensing, or other commercial interest in the subject matter under consideration in the guideline under review. Disclosures include employment, paid consulting or advisory roles, stock ownership, honoraria, research funding, gifts, and other payments from affected companies received by panel members themselves and their immediate family members.²

Prospective panel members will be asked to disclose at the time of nomination by the Clinical Practice Guideline Committee. Generally, the list of affected companies will be provided at the time of disclosure. Prospective panel members will be asked to identify any financial interests in affected companies already listed, as well as any other relationships that are relevant to the guideline under review. It does not matter whether a financial relationship relates to the subject matter of the guideline.

Occasionally, a panel member may have a relevant financial interest or relationship that is not covered by ASCO's formal disclosure process, such as a patent in a product referenced in the guideline. In these situations, the panel member should disclose this interest to the panel chair or co-chair, or appropriate ASCO staff member.

Panel disclosure reports identifying relationships with affected companies will be available to panel members throughout the guideline development process. In addition, panel disclosure reports will be made available to the Clinical Practice Guideline Committee and the ASCO Board of Directors before they vote to approve or adopt a guideline.

b. Selection of Panel Chairs and Co-Chairs

Generally, the Clinical Practice Guideline Committee will not appoint chairs and co-chairs who have financial interests in or relationships with affected companies or products. This includes all relationships described in Section II.a. However, the Committee may name a panel chair who receives research funding from an affected company if doing so would ultimately help the panel develop a better quality guideline. In this case, the Clinical Practice Guideline Committee must appoint a co-chair who has no ties to affected companies, including research funding.

These restrictions apply to the activities and interests of panel chairs and co-chairs for a period of one year prior to the commencement of panel deliberations through one year after the guideline is published.

² American Society of Clinical Oncology: Revised Conflict of Interest Policy. J Clin Oncol 24:10.1200/JCO.2005.04.8926. Also available at www.asco.org/conflictofinterest

If a panel chair or co-chair wants to continue to serve as chair for future guideline updates, he or she must remain in compliance with these restrictions. If, at the time of update, an individual is no longer eligible to serve as a chair because of financial relationships, he or she will be eligible to serve as a panel member at the discretion of the Clinical Practice Guideline Committee.

c. Selection of Panel Members

At least 51% of those selected to serve on a panel will have no relationships with affected companies from the start of panel deliberations through publication of the guideline. For the remaining 49%, such financial relationships do not preclude panel membership. All relationships with affected companies must be disclosed. In rare circumstances the Clinical Practice Guideline Committee may determine that an individual is not eligible to serve as part of the 49% of the panel because of the nature and extent of his or her financial relationship with an affected company.

d. Voting

At in-person meetings, panel recommendations must be adopted by a 75% majority of panel members in attendance at a meeting where a simple majority of panel members are present. When the panel votes electronically, recommendations must be adopted by a 75% majority of the entire panel.

Because of the supermajority voting standard, panel members who have financial relationships with affected companies do not need to recuse themselves from discussing and voting on guideline recommendations on these grounds. Rarely, relationships may be disclosed that, though not financial in nature, could undermine public confidence in the guideline process. If there is a question as to whether a particular relationship warrants recusal, a determination will be made by the panel chair, with the assistance of an appropriate ASCO staff member.

e. Publication of Disclosure Information

When ASCO publishes a guideline in one of its journals, all disclosures of panel members will generally be published concurrently.

III. Clinical Practice Guideline Committee

a. Disclosure

Clinical Practice Guideline Committee members disclose financial interests and other relationships with entities that have an investment, licensing, or other commercial interest in the science or practice of oncology. Disclosures include employment, paid consulting or advisory roles, stock ownership, honoraria, research funding, gifts, and other payments received by panel members themselves and their immediate family members. These

disclosures will be compared with the list of affected companies before a guideline is reviewed by the Clinical Practice Guideline Committee.

Occasionally, a Clinical Practice Guideline Committee member may have a relevant financial interest or relationship that is not covered by ASCO's formal disclosure process, such as a patent in a product referenced in the guideline. In these situations, the Clinical Practice Guideline Committee member should disclose this interest to the Committee Chair or appropriate ASCO staff member prior to discussion of the guideline.

Committee disclosure reports identifying relationships with affected companies will be available to Clinical Practice Guideline Committee members prior to Committee discussion of a guideline. The Clinical Practice Guideline Committee's disclosure report may also be made available to the ASCO Board of Directors before the Board votes to adopt a guideline.

b. Clinical Practice Guideline Committee Reviewers

From time to time the Clinical Practice Guideline Committee Chair appoints Committee members to serve as reviewers of a guideline. Generally, the Committee Chair will select Committee members who have no financial relationships with affected companies or products to serve as guideline reviewers.

c. Recusal

To underscore the independence and integrity of the guideline adoption process, guidelines will be approved only by Clinical Practice Guideline Committee members who do not have financial relationships with affected companies or products. Therefore, disclosure of any financial relationship with an affected company or product as described in Section III.a. should be cause for recusal.

Rarely, relationships may be disclosed that, though not financial in nature, could undermine public confidence in the guideline process. If there is a question as to whether a particular relationship warrants recusal, a determination will be made by the Clinical Practice Guideline Committee Chair, with the assistance of an appropriate ASCO staff member. Whether a financial relationship relates to the subject matter of the guideline is not a relevant consideration for purposes of determining recusal.

Any Committee member who discloses a financial interest in a company or product affected by a guideline should recuse him or herself from the Committee's decision on approval of a guideline. Such a Committee member may take part in initial Committee discussion of the guideline manuscript, recognizing that there may be additional discussion by remaining Committee members after recusal and before the vote.

d. Voting

Generally, guidelines will be reviewed and approved by a vote of the Clinical Practice Guideline Committee at a meeting where a quorum is present.

However, the Committee has delegated its authority to one or more subgroups of the Committee to act when the Committee lacks a quorum to approve a guideline due to refusal. The Committee will authorize the Committee Chair to appoint, from time to time, an ad hoc subgroup to discuss a guideline and vote on approval of the guideline. The subgroup for a guideline should be comprised of Committee members who do not have financial relationships with affected companies or products.

A subgroup may convene at a Committee meeting where a guideline is scheduled for review, or any time before or after, in person or by teleconference. A majority vote of the subgroup is required to approve a guideline. Approval by the subgroup will be considered approval by the Clinical Practice Guideline Committee, and full Committee review will not be needed.

IV. Board of Directors

a. Disclosure

ASCO Board members already disclose financial interests and other relationships with entities that have an investment, licensing, or other commercial interest in the science or practice of oncology.³ Disclosures include employment, paid consulting or advisory roles, stock ownership, honoraria, research funding, gifts, and other payments received by panel members themselves and their immediate family members. These disclosures will be compared with the list of affected companies before a guideline is reviewed by the Board.

Occasionally, a Board member may have a relevant financial interest or relationship that is not covered by ASCO's formal disclosure process, such as a patent in a product referenced in the guideline. In these situations, the Board member should disclose this interest to the President or Ethics counsel prior to discussion of the guideline. Board disclosure reports identifying affected companies will be available to the Board members considering adoption of a guideline.

b. Board Reviewers

From time to time the President appoints Board reviewers of a guideline. Generally, the President will select Board members who have no financial relationships with affected companies or products to serve as guideline reviewers.

³ Implementation of ASCO's Conflict of Interest Policy for ASCO Leadership, approved by the ASCO Board of Directors, June 8, 2006

c. Recusal

To underscore the independence and integrity of the guideline adoption process, guidelines will be adopted only by Board members who do not have financial relationships with affected companies or products. Therefore, disclosure of any financial relationship with an affected company or product as described in Section IV.a. should be cause for recusal.

Rarely, relationships may be disclosed that, though not financial in nature, could undermine public confidence in the guideline process. If there is a question as to whether a particular relationship warrants recusal, a determination will be made by the Vice President and General Counsel. Whether a financial relationship relates to the subject matter of the guideline is not a relevant consideration for purposes of determining recusal.

Any Board member who discloses a financial interest in a company or product affected by a guideline should recuse him or herself from the Board's decision on adoption of a guideline. Such a Board member may take part in initial Board discussion of the guideline manuscript, recognizing that there may be additional discussion by remaining Board members after recusal and before the vote.

d. Voting

Generally, guidelines will be reviewed and adopted by a vote of the ASCO Board of Directors or Board Executive Committee at a meeting where a quorum is present.

However, the Board has delegated its authority to one or more subgroups of the Board to act when the Board or Executive Committee lacks a quorum to adopt a guideline due to recusal. The Board will authorize the President to appoint, from time to time, an ad hoc subgroup to vote on adoption of the guideline. The subgroup for a guideline should be comprised of Board members who do not have financial relationships with affected companies or products.

A subgroup may convene at a Board meeting where a guideline is scheduled for review, or any time before or after, in person or by teleconference. A majority vote of the subgroup is required to adopt a guideline. Adoption by the subgroup will be considered adoption by ASCO, and full Board review will not be needed.

V. *JCO* Peer Review

JCO Editors and reviewers disclose financial interests and other relationships in a manner that is consistent with the ASCO Conflict of Interest Policy and the practices and procedures set by the *Journal*. Disclosures include employment, paid consulting or advisory roles, stock ownership, honoraria, research funding, gifts, and other payments from affected companies. The disclosures of all *JCO* Editors are published annually on the *JCO* website (www.jco.org).

JCO Editors and reviewers may decline to review a guideline due to potential conflicts of interest.

VI. Exceptions

ASCO's goal is to assemble a diverse and well-qualified group of experts to develop, approve, and adopt guideline recommendations. If required to achieve this goal, these procedures may be adapted by the Clinical Practice Guideline Committee, the President, or the Executive Vice President and Chief Executive Officer on a case-by-case basis to the extent necessary.