



Conflict of Interest Policy Implementation for Clinical Practice Guidelines¹ of American Society of Clinical Oncology

(August 8, 2013)

The American Society of Clinical Oncology (ASCO) is dedicated to conquering cancer through research, education, prevention and delivery of high-quality patient 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. Provider and 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 ASCO's Clinical Practice Guideline Committee (Committee) 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 (COI) through each phase of guideline development, in accordance with ASCO's Policy for Relationships With Companies.²

I. General Policy

ASCO requires COI disclosure by individuals involved in drafting, reviewing, and approving guideline recommendations and sets limits on the financial relationships that panel members and reviewers can have with Companies that could reasonably be affected by care delivered in accordance with guideline recommendations.

As a signatory Society to the Council of Medical Specialty Societies Code for Interactions with Companies³ (CMSS Code), ASCO requires the majority of panel members (51%), including the panel chair, to be free of certain relationships with affected Companies. The remaining 49% of panel members may be appointed to a panel if they hold some relationships with affected

Companies. ASCO adopts the CMSS Code definition of "Company." A Company is a for-profit entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions.⁴

¹ History: 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.

² American Society of Clinical Oncology, Policy for Relationships With Companies 2013 JCO2013.49.5002 <http://jco.ascopubs.org/content/31/16/2043.full>

³ Council of Medical Specialty Societies, Code for Interactions with Companies. www.cmss.org/codeforinterations.aspx

⁴ Council of Medical Specialty Societies, Code for Interactions with Companies. www.cmss.org/codeforinterations.aspx

II. Identifying Affected Companies

Companies with products affected by a guideline are considered “affected Companies” for purposes of determining whether a conflict of interest exists in the development of ASCO guidelines. A Company 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. 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.

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 Quality and Guidelines Department or the Chief Medical Officer 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 and the Clinical Practice Guideline Committee.

III. Disclosure

ASCO’s policy is to promote the development of clinical practice guidelines in a manner that minimizes the risk of actual and perceived bias. Disclosure of relationships with Companies is the first step in ASCO’s process of evaluating and managing relationships that could result in actual or perceived bias.

a. General COI Disclosure

All prospective panel members, including prospective panel chairs and co-chairs, will disclose financial interests and other relationships with Companies in accordance with ASCO’s Policy for Relationships With Companies.⁵ All Committee members disclose the same information. These disclosures are general and may or may not identify relationships with affected Companies. Disclosure categories include compensation received for employment, leadership positions, consulting activities, speaking engagements, and expert testimony; as well as ownership interests, research funding (to the individual or the institution), and licensing fees and royalties associated with intellectual property interests received by panel or Committee members themselves and their immediate family members.⁶

An individual’s COI disclosures must be current in ASCO’s electronic system prior to appointment to a panel. Panel members and Committee members must keep their COI disclosures up to date.

⁵ American Society of Clinical Oncology, Policy for Relationships With Companies 2013 JCO2013.49.5002 <http://jco.ascopubs.org/content/early/2013/04/22/JCO.2013.49.5002>

⁶ American Society of Clinical Oncology, Policy for Relationships With Companies 2013 JCO2013.49.5002 <http://jco.ascopubs.org/content/early/2013/04/22/JCO.2013.49.5002>

b. Additional Disclosure

After reviewing the general disclosures and the list of affected Companies, the Committee Chair or ASCO staff may request more detailed information from an individual about the nature, value, or extent of his or her disclosed relationship with an affected Company in order to apply this Policy.

Occasionally, an individual may have a relevant indirect or non-financial interest or relationship that is not covered by ASCO's general COI disclosure, such as an intellectual property interest from which no royalties or other payments have yet been received; a strong professional or research opinion; or an outside affiliation. In these situations, the interest should be disclosed to the panel chair or co-chair or appropriate ASCO staff member.

Disclosure reports identifying panel members' relationships with affected Companies will be available to panel members throughout the guideline development process. The Committee will have this information available when considering guideline recommendations.

IV. Guideline Panels

ASCO's goal is to assemble a diverse and well-qualified group of experts to develop, approve, and adopt guideline recommendations in a manner that minimizes the risk of actual and perceived bias.

a. Not Eligible to Serve on Panel

Having a relationship with a Company does not necessarily mean an individual is biased or has a conflict of interest. However, ASCO's policy is that certain financial relationships give rise to conflicts of interest that are not capable of being effectively managed and are, in fact, inconsistent with actual and perceived independence in the guideline development process. An individual is not eligible to serve on a clinical practice guideline panel if he or she:

1. participates in a speakers' bureau⁷ (on any subject) on behalf of an affected Company;
2. is employed by an affected Company, or has been employed by an affected Company at any time during the year prior to appointment to the panel and to continue for one year after the publication of the guideline; or
3. holds a significant ownership interest in an affected Company⁸; or

⁷ "Speakers' bureau" means a compensated role as a presenter for which any of the following criteria are met: (a) a Company has a contractual right to dictate or control the content of the presentation or talk; (b) a Company creates the slides or presentation material and has final approval of the content and edits; or (c) the presenter is expected to act as a Company's agent or spokesperson for the primary purpose of disseminating company or product information. ASCO recognizes that some activities called "speakers' bureaus" may not meet these criteria and, conversely, that activities may meet these criteria and not be termed "speakers' bureaus." ASCO will rely on the judgment and integrity of disclosing individuals to determine whether an activity constitutes a speakers' bureau under this Policy. This definition of "speakers' bureau" does not extend to employees of a Company who make presentations as part of their employment.

4. holds a financial or other relationship whether with an affected Company or another interest that, in ASCO's discretion, presents a risk of actual or perceived bias that cannot be effectively managed or could undermine public confidence in the guideline.

b. Eligible to Serve as Panel Chair or Co-Chair

Generally, individuals who have disclosed financial interests in or relationships with affected Companies will not be appointed as panel chairs or co-chairs. A panel chair or co-chair must have been free of all interests and relationships for one year prior to appointment as chair and remain free of these interests and relationships at all times during the panel's work and through one year after the guideline is published.

However, the Committee may appoint one 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 Committee must appoint a co-chair who has no relationships with affected Companies, including research funding.

If a panel chair or co-chair wants to continue to serve as chair for future guideline updates, he or she must remain eligible as described above. If, at the time of update, an individual is no longer eligible to serve as a chair, he or she will be eligible to serve as a panel member at the discretion of the Clinical Practice Guideline Committee and in accordance with this Policy Implementation.

c. Eligible to Serve in the Panel Majority

In accordance with the CMSS Code, a majority of ASCO guideline panel members must be free of conflicts of interest relevant to the subject matter of the guideline. All relationships with Companies must be disclosed as described in Section IIIa. The Committee Chair or ASCO staff may ask for additional information about a relationship with an affected Company, as described in Section IIIb, to apply this Policy Implementation.

For the purpose of appointing at least 51% of guideline panel members who are free of conflicts of interest, ASCO defines the following relationships as conflicts of interest:

1. Research funding from an affected Company, paid to the individual or his or her practice or institution if:
 - a. research payments are made directly from the affected Company to the individual;
 - b. the individual's salary is supported (in whole or part) through a research grant from an affected Company;
 - c. the individual is a national or overall principal investigator for a study funded by an affected Company;
 - d. the individual is a member of a steering committee of a study that does not have a principal investigator.⁹
2. Compensation (including honoraria) from any one affected Company that equals, in aggregate, \$5,000¹⁰ or more in a calendar year.

⁸ "Significant ownership interest" means shares of a publicly traded Company greater than \$50,000 in value or an equity interest in a privately held Company greater than 5% at the time of disclosure. This does not include interests invested in diversified funds whose holdings cannot be controlled by the disclosing individual.

⁹ Serving as a site or local PI, or a consortium PI without salary support are not considered conflicts of interest.

- a. This includes fees and honoraria for leadership positions, consulting activities, speaking engagements, expert testimony, and patent or other licensing fees.
- b. This excludes any compensation provided under any of the circumstances described in Section IV.a.

Individuals with any of these relationships are not eligible to serve in the panel majority, but may be eligible to serve in the panel minority. A member of the panel majority must remain free of these conflicts of interest from the time of his or her appointment to the panel through the end of the calendar year in which the guideline is published. If an individual's relationships change during that period such that he or she is no longer eligible to serve in the panel majority, the Committee chair will shift the individual to the panel minority. If that is not feasible given the panel composition, the individual must resign from the panel.

If an individual holds a patent in a technology that could be part of a guideline recommendation, the individual may be eligible to serve on the panel minority as described in Section IVc with special requirements for COI management, or ASCO may find the individual ineligible to serve on the panel under Section IVa.4 above.

If an individual holds stock options in an affected Company, as defined in Section II above, the individual may be eligible to serve on the panel minority as described in Section IVc with special requirements for COI management, or ASCO may find the individual ineligible to serve on the panel under Section IVa.4 above.

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 disclosed financial relationships with affected Companies do not need to recuse themselves from discussing and voting on guideline recommendations on these grounds.

V. Clinical Practice Guideline Committee

a. Disclosure

Committee members will generally disclose financial relationships with Companies as described in Section IIIa and make additional disclosures as described in Section IIIb. These disclosures will be compared with the list of affected Companies before a guideline is reviewed by the Committee.

Committee members' general disclosure reports, identifying relationships with affected Companies, will be available to Clinical Practice Guideline Committee members prior to Committee discussion of a guideline.

¹⁰ This dollar value may be updated periodically to keep pace with current standards.

b. Clinical Practice Guideline Committee Reviewers

From time to time the 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 Committee members who do not have financial relationships with affected Companies or products. Therefore, disclosure of any financial relationship with an affected Company should be cause for recusal. Whether a relationship relates to the subject matter of the guideline is not a relevant consideration for purposes of determining recusal.

A Committee member recused from voting 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 Committee at a meeting where a quorum is present. However, if the quorum is lost by virtue of recusals as described in Section Vc, the remaining Committee members in attendance will constitute a quorum as long as at least three voting members are present. Approval by majority vote of this group will be considered approval by the Committee.

VI. Guideline Advisory Groups

Guideline Advisory Groups (Advisory Groups) make recommendations to the Clinical Practice Guideline Committee on identifying and prioritizing topics for guideline development, provide strategic direction in the development of guidelines, and provide recommendations regarding possible third party guideline endorsement and joint guideline endeavors.

a. Disclosure

Advisory Group members will generally disclose financial relationships with Companies as described in Section IIIa and make additional disclosures as described in Section IIIb.

1. When making general or strategic recommendations to the CPGC, Advisory Group members' general disclosure reports will be available to Clinical Practice Guideline Committee members prior to Committee discussion.
2. When making recommendations to the CPGC on a specific topic or disease site, Advisory Group members' general disclosure reports, identifying relationships with affected Companies, will be available to Clinical Practice Guideline Committee members prior to Committee discussion.

b. Eligible to Serve as Guideline Advisory Group Chair, Co-Chair, or Member

Advisory Group Co-Chairs (two per group) are appointed by the Clinical Practice Guideline Committee Leadership. Groups consist of members of the Clinical Practice Guidelines Committee, other disease site content experts, and consumer representatives. Eligibility restrictions for Chairs, Co-Chairs, or members of Guideline Panels described in Section IV do not apply to Guideline Advisory Groups. Invitations to participate are made at ASCO's discretion.

VII. Publication and Peer Review

When ASCO publishes a guideline in one of its journals, all disclosures of panel members will generally be published concurrently. This Policy Implementation is also posted publicly on ASCO's website.

JCO Editors and reviewers disclose financial interests and other relationships in a manner that is consistent with the ASCO Policy for Relationships With Companies and the practices and procedures set by the *Journal*. The disclosures of all *JCO* Editors are published on the *JCO* website (www.jco.org). *JCO* Editors and reviewers may decline to review a guideline due to potential conflicts of interest.

VIII. Joint Guidelines and ASCO-Endorsed Guidelines

From time to time, ASCO may join another organization to create a guideline or may endorse a relevant guideline produced by another organization. In these instances, the COI management procedures used for the development of the joint or endorsed guideline must meet the requirements of CMSS Code for Interactions with Companies, as a baseline.¹¹

IX. 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 ASCO on a case-by-case basis to the extent necessary.

X. Decisions

Questions about the application of this Policy Implementation will be decided by ASCO. ASCO will consider recommendations from the panel chair and co-chair and the Committee Chair (unless the question concerns their roles). ASCO decisions can be made by the Chief Medical Officer or the Vice President and General Counsel, advised by the Associate Counsel for Ethics and Senior Director, Quality and Guidelines. Questions and decisions may concern, for instance, whether an individual is eligible to serve on a panel, or as a panel chair or co-chair, or in a panel

¹¹ Council of Medical Specialty Societies, Code for Interactions with Companies. www.cmss.org/codeforinteractions.aspx

majority, or as a Committee reviewer; whether an individual should be recused from voting; or whether an exception is warranted.

Application:

Applies to ASCO

History:

Adopted by the ASCO Board of Directors on December 3, 2007

Amended on August 8, 2013