

<b>Policy Name:</b> Conflict of Interest Policy for Clinical Practice Guidelines <sup>1</sup> of American Society of Clinical Oncology
<b>Policy Number:</b> COI-006
<b>Policy applies to:</b> Society and Affiliates
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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. 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 Evidence Based Medicine Committee (EBMC) and peer-reviewed in accordance with rigorous standards set by the *Journal of Clinical Oncology (JCO)* or the *Journal of Clinical Oncology Global Oncology (JCO GO)*. 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.<sup>1</sup> Together, these policies constitute the Conflict of Interest Policy for Clinical Practice Guidelines (“Policy”). This Policy applies to all ASCO guideline products, including resource-stratified guidelines, rapid updates, living guidelines, Provisional Clinical Opinions (PCOs), and other guideline products described in the ASCO Guidelines Methodology Manual, which may be updated from time to time with the approval of the Society Board of Directors.

## 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.

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<sup>1</sup> 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. An updated version of this policy was adopted by the ASCO Board of Directors on August 13, 2013.

As a signatory Society to the Council of Medical Specialty Societies Code for Interactions with Companies<sup>2</sup> (CMSS Code), ASCO requires the majority of panel members (51%), including at least one panel Co-Chair, to be free of conflicts of interest 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.<sup>3</sup>

## **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 or Co-Chairs.

An affected Companies list will generally be drafted by an ASCO Guidelines Specialist in consultation with ad hoc experts who will not serve as a panel member or guideline reviewer. 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, the list may be modified during guideline development. The list of Companies affected by a guideline will be made available to prospective guideline panel Chairs and panel members and the EBMC and will be available to all panel members throughout the development of the guideline. If the list is modified during the development of the guideline, the panel composition will be checked to maintain compliance with this Policy.

## **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 Co-Chairs, will disclose financial interests and other relationships with Companies in accordance with ASCO’s Policy for Relationships With Companies.<sup>1</sup> All EBMC 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.<sup>1</sup>

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.

#### **b. Additional Disclosure**

After reviewing the general disclosures and the list of affected Companies, the Committee Co-Chairs or ASCO staff may request more detailed information from an individual about the nature, value, or extent of their disclosed relationship with an affected Company or other entity 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 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' bureau (on any subject) on behalf of an affected Company;
2. is employed by a for-profit healthcare 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 Company; or
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 Co-Chair**

Generally, individuals who have disclosed relationships with affected Companies, deemed to be disqualifying by ASCO (listed in Section IV.a. above), will not be appointed as panel Chairs or Co-

Chairs. Panel Co-Chairs should be free of all such relationships for one year prior to appointment as Co-Chair and remain free of these relationships at all times during the panel's work through to publication and for one year after the guideline is published.

The Committee may appoint one panel Co-Chair who receives 1) research funding, and/or 2) less than \$10,000 in compensation annually for honoraria or consultancy/advisory role per affected Company, if doing so would ultimately help the panel develop a better quality guideline. One Co-Chair must be free of relationships with any affected Companies, including research funding.

If a panel Co-Chair wants to continue to serve as Chair for future guideline updates, they must remain eligible as described above. If, at the time of update, an individual is no longer eligible to serve as a Chair, they may be eligible to serve as a panel member at the discretion of the EBMC and in accordance with this Policy.

#### **c. Eligible to Serve in the Panel Majority**

In accordance with the CMSS Code, a majority (at least 51%) of ASCO guideline panel members (including Co-Chairs) must be free of conflicts of interest with affected companies as determined by ASCO. The Committee Chair or ASCO staff may ask for additional information about a relationship with an affected Company. An individual is considered eligible to serve in the panel majority if:

1. they do not have any disqualifying relationships with affected Companies, as outlined in Section IVa;
2. they do not have any disqualifying research funding (Section IVd1)
3. they do not receive more than \$10,000 in compensation annually per affected Company for honoraria or consultancy/advisory role;
4. they do not receive funding research from an affected Company with salary support as a site, local, or consortium principal investigator (PI).

A member of the panel majority must remain free of these relationships with affected companies from the time of their appointment to the panel through the date of guideline publication. Panel members should decline offers from affected Companies to speak about the guideline on behalf of the Company for a one-year period after publication.

#### **d. Eligible to Serve in the Panel Minority**

In accordance with the CMSS Code, a minority (at most 49%) of ASCO guideline panel members may have certain relationships with affected Companies.

An individual is considered eligible to serve in the panel minority if:

1. They receive research funding or grants from an affected Company if the individual receives payments directly from an affected Company or if their institution or practice

receives payments from an affected Company that directly supports their salary in whole or part. Examples include:

- a. The individual is a national or overall PI for a study funded by an affected Company;
  - b. The individual is a member of a steering committee of a study funded by an affected Company that does not have a principal investigator
  - c. The individual is a site or local PI, or consortium PI with salary support.
2. They receive compensation from any one affected Company that equals or exceeds, in aggregate, \$10,000 in a calendar year. This compensation includes fees and honoraria for leadership positions, consulting activities, speaking engagements, expert testimony, and patent or other licensing fees. This excludes any compensation provided under any of the circumstances described in Section IVa.
  3. They have any relationship with an affected Company or other professional engagement 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.
  4. They have patents in technologies that could be part of a guideline recommendation. This will be addressed on a case-by-case basis at ASCO's sole discretion. An individual holding a patent may be eligible to serve on the panel minority with special requirements for COI management, or ASCO may find the individual ineligible to serve on the panel.
  5. They have ownership interests falling below the "significant" threshold as defined by ASCO (See Section XI herein for definitions). This will be addressed on a case-by-case basis at ASCO's sole discretion. An individual with an ownership interest below the threshold may be eligible to serve on the panel minority with special requirements for COI management, or ASCO may find the individual ineligible to serve on the panel.

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 guideline publication. Panel members should decline offers from affected Companies to speak about the guideline on behalf of the Company for a one-year period after publication.

If an individual's relationships change during the development of the guideline 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.

#### **e. Additional Considerations**

In composing an effective guideline panel, ASCO considers all relationships of prospective panel members, whether with an affected Company or other professional engagement 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. There are several categories of professional activities that will be considered on a case-by-case basis, including but not limited to these examples:

1. In Kind Contributions- In-kind contributions for an individual's services or expertise that

are made in lieu of wages or cash payments will be considered as direct financial relationships. In-kind contributions such as patient care items, patient samples, and study drugs may not be considered direct financial relationships.

2. Travel, lodging, food and beverage- Acceptance of reasonable travel reimbursement and reasonable meals in connection with uncompensated service is acceptable provided the relationship is otherwise permissible for the individual under this Policy.
3. Funding from non-profit organizations- Non-profit entities, entities outside of the healthcare sector, government agencies, or entities through which physicians provide clinical services directly to patients are not considered to be affected Companies for the purpose of guideline panel composition. However, non-profit foundation affiliated with or controlled by an affected Company may be considered as the Company for the purpose of transparent and effective management of potential conflicts of interest, at ASCO's sole discretion. Panel members and potential panel members are encouraged to discuss this issue with ASCO staff.

#### **f. Voting**

Guideline recommendations must be adopted by a 75% majority of panel members, whether during a meeting or electronically.

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.

#### **g. Maintaining Eligibility of a Co-Chair or Panel Member**

Panel members and Co-Chairs are expected to maintain their eligibility under this Policy at all times during the panel's work through to publication and, wherever possible, for one year after the guideline is published. If, after their appointment, a panel member or Co-Chair acquires a new relationship with an affected Company that is prohibited by this Policy or later discloses a relationship that is prohibited by this Policy, they will be considered ineligible and may be required to step down from the panel or the Co-Chair role. If necessary to maintain compliance with this Policy, ASCO retains the right to remove panel members or Co-Chairs. Removal of Co-Chairs could impact authorship position if another Panel member must move into the Chair role to complete the work of the guideline. ASCO Guidelines follow ASCO Journal authorship policies.

### **V. Evidence Based Medicine 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 EBMC members prior to Committee discussion of a guideline.

## **b. Evidence Based Medicine Committee Reviewers**

The Committee Chair will appoint two to three Committee members to serve as reviewers of a guideline. Generally, the Committee Chair will select Committee members or other expert reviewers who have no financial relationships with affected Companies or products to serve as guideline reviewers. Members who are eligible serve as EBMC reviewers and vote on the guideline must not have relationships with affected companies two years prior to EBMC submission

## **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**

Committee members who have no relationships with affected Companies are eligible to vote. Committee members who have relationships with affected Companies are recused from voting, but they are encouraged to participate in the deliberations. 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 (AGs) make recommendations to the EBMC 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**

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

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

Advisory Group Co-Chairs (two per group) are appointed by the EBMC Leadership. Groups consist of members of the EBMC, other disease site content experts, and consumer representatives. Eligibility restrictions for 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.

Editors of ASCO Journals 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 ASCO Journal Editors are published on their websites ([www.ascopubs.org](http://www.ascopubs.org)). ASCO Journal 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.<sup>3</sup>

## 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 Co-Chairs 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 Vice President of Policy and Advocacy. Questions and decisions may concern, for instance, whether an individual is eligible to serve on a panel, or as panel Co-Chairs, or in a panel majority, or as a Committee reviewer; whether an individual should be recused from voting; or whether an exception is warranted.

## XI. Definition of Terms

Term	Definition
Affected Company	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 <i>direct regulatory or commercial impact (positive or negative)</i> on the entity as a result of care delivered in accordance with guideline recommendations.
Direct Financial Relationship	A Direct Financial Relationship is a relationship held by an individual that results in wages, consulting fees, honoraria, or other compensation



	(in cash, in stock or stock options, or in kind), whether paid to the individual or to another entity at the direction of the individual, for the individual's services or expertise
Speakers Bureau	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.
Speaking Engagement	Unlike speakers bureau, the presenter has control over the content of the presentation. A speaking engagement may be an educational activity where an honoraria is paid.
Significant Ownership	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.
Company	For-profit health care company means a business that develops, produces, markets or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions.
Consultancy or Advisory Role	The provision of any services, including advisory boards, scientific review, or editorial services. You do not need to disclose an uncompensated consulting or advisory role.
Honoraria	Money paid to recognize participation in an activity such as a speech or seminar presentation. You do not need to disclose honoraria for certified Continuing Education.

## References

1. American Society of Clinical Oncology: American Society of Clinical Oncology: Policy for relationships with companies. J Clin Oncol 31:2043-6, 2013
2. Council of Medical Specialty Societies: CMSS Principles for the Development of Specialty Society Clinical Guidelines, 2017
3. Council of Medical Specialty Societies: Code For Interactions With Companies, 2015