

Managing Conflicts of Interest in the Development of Clinical Practice Guidelines

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AMERICAN SOCIETY OF CLINICAL ONCOLOGY

ASCO Conflict of Interest Policy

An Authoritative Resource

Public confidence in our guidelines depends on the cultivation of expert opinions based on the best available evidence, in a manner designed to minimize actual and perceived conflicts of interest. ASCO is committed to developing policies and procedures that support this effort.

Guideline Development and Review Process

- § Systematic review of evidence
- § Panel of content experts, guideline experts, patient advocates, etc.
- § Outside Reviewers
- § *Journal of Clinical Oncology* Reviewers
- § JCO Associate Editor/ HSC Chair
- § Health Services Committee and Reviewers
- § Board Reviewers
- § Board adoption, and submission to JCO
- § JCO Editor's decision on JCO publication

3

Conflict of Interest Plan for Guidelines

Rigorous Peer Review

- § Guidelines subject to extensive and rigorous peer review by ASCO members, non-ASCO content experts, HSC members, Board members, and JCO Editors and reviewers
- § Over 100 reviewers may evaluate a single guideline

ASCO Conflict of Interest Policy

- § First adopted by the Board in 1994
- § Applies to leadership, staff, volunteers, presenters, and authors
- § Requires disclosure at first dollar; some restrictions on relationships
- § Comprehensive implementation plan for guidelines addresses each phase of the review and approval process

Conflict of Interest Plan for Guidelines

Affected Company

- § Commercial entity
- § Reasonable likelihood of direct regulatory or commercial impact (positive or negative) as a result of care delivered in accordance with guideline recommendations

Conflict of Interest Plan for Guidelines

Panel Composition and Voting

- § Majority of Panel members with no relationships
- § No relationships allowed for Panel chairs
- § Supermajority approval (>75%) of all panel recommendations

Conflict of Interest Plan for Guidelines

Health Services Committee and Board Approval

- § Only Health Services Committee and Board members without relationships vote to approve a guideline
- § Approved guidelines submitted to JCO for independent review; can be rejected
- § Disclosure is published

Conflict of Interest Plan for Guidelines

Additional Safeguards

- § Rigorous development and review process
- § Based on scientific evidence
- § Panel composition and voting requirements eliminate potential for influence
- § Disclosure published with guideline
- § Outstanding reputation: we have never had to retract a single recommendation

Conflict of Interest Plan for Guidelines

Challenges?

- § Defining affected companies
- § Interpreting disclosure rules
- § Finding a balance – professionals vs. acknowledged experts
- § Panel members' frustration with “hoops” and negative connotation of relationships

Institutional Firewalls

ASCO's Conflict of Interest Policy is part of a broad framework of institutional firewalls that help to ensure that ASCO's programs and decisions are guided by the needs of patients, and are independent from funding sources.

Moving Forward

- § Policies are Changing Behavior: increased buy-in of members and colleagues
- § Self-regulation in academe and industry; move toward greater transparency
- § Institutional firewalls can allow ASCO to pursue its mission independently and in perpetuity

Summary

- § ASCO began a rigorous debate about Conflicts of Interest over 10 years ago
- § These are difficult conversations about member perception, public perception, and the nature of clinical science
- § We must maintain constant focus on these issues with an eye toward continuous improvement of our policies and behavior
- § Our reputation as an independent and objective voice rests on getting this right

13