American Society of Clinical Oncology: Policy for Relationships With Companies

American Society of Clinical Oncology

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I. INTRODUCTION

The American Society of Clinical Oncology ("the Society") is dedicated to conquering cancer through research, education, prevention, and the delivery of high-quality cancer care, and is a trusted source for cancer information worldwide. Confidence in the integrity of the Society's cancer education, information resources, and practice tools is enhanced by maintaining independence and transparency in financial relationships with Companies. ASCO demonstrates its commitment to these values by disclosing, managing, and, in some cases, restricting financial relationships that could be perceived to compromise its objective voice. ASCO also facilitates rigorous peer review of research abstracts, journal articles, clinical practice guidelines, and other content.

The following Policy for Relationships with Companies ("Policy") describes ASCO's comprehensive approach to addressing financial relationships held by ASCO, its key leaders and volunteers, and anyone who seeks to publish or present in an ASCO forum.

II. IMPLEMENTATION

A. Application of Policy to the Society and Affiliated Entities

This Policy applies to the activities of the Society and its affiliates, including the Conquer Cancer Foundation ("CCF") and the Institute for Clinical Excellence, unless specific terms or the context dictate otherwise. This Policy also applies to Journal of Clinical Oncology ("JCO") and Journal of Oncology Practice ("JOP"). For purposes of this Policy, the term "ASCO" refers to all of these entities and publications, collectively and as applicable.

B. Related Codes and Implementation Plans

The Council of Medical Specialty Societies Code for Interactions With Companies ("CMSS Code") is a set of principles that requires signatory societies to adopt policies for transparency and independence in transactions and activities involving for-profit entities that develop, produce, market, or distribute drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions. ASCO signed on to the CMSS Code in April 2010 with the support of CCF and has adopted policies and practices in compliance with the Code.

In its programs, publications, and activities, ASCO addresses the management of relationships with Companies through written Implementation Plans and a range of procedures consistent with this Policy. Implementation plans and specific policies and procedures may be adopted by ASCO from time to time. Some Implementation Plans are summarized below and are publicly available.

C. Conflict of Interest Implementation Plans for Leadership

ASCO's Conflict of Interest Implementation Plans for Leadership set out the disclosure requirements for members of the Society and CCF Boards of Directors, as well as restrictions on financial and other relationships held by Board members, the Chief Executive Officer, the Chief Medical Officer, and the Editors-in-Chief of JCO and JOP.

D. Conflict of Interest Policy for Officers, Directors, and Key Employees

The Society's and CCF's Conflict of Interest Policies for Officers, Directors, and Key Employees govern disclosure and management of financial relationships held by interested persons in accordance with Internal Revenue Service standards for tax-exempt organizations and good corporate governance practices.

E. Conflict of Interest Policy Implementation Plan for Continuing Medical Education (CME) Activities

As an accredited provider of continuing medical education (CME) for physicians, the Society offers CME in accordance with the Accreditation...
Council for Continuing Medical Education Standards for Commercial Support. ASCO’s Conflict of Interest Policy Implementation Plan for CME Activities sets out disclosure requirements and management strategies for relevant financial relationships held by planners, presenters, and other individuals who are in a position to control the content of Society CME.

F. Conflict of Interest Policy Implementation for Clinical Practice Guidelines

ASCO’s policy is to promote the development of clinical practice guidelines, guidance, quality measures, and practice tools in a manner that minimizes the risk of actual and perceived bias. ASCO’s Conflict of Interest Policy Implementation for Clinical Practice Guidelines sets out the disclosure requirements for panel members and others 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 that is delivered in accordance with guideline recommendations (“Affected Companies”). Among other requirements, the majority of panel members, including the panel chair, must not hold relevant relationships with Affected Companies. ASCO does not accept Company funding to support the development or initial publication or dissemination of clinical practice guidelines or similar practice tools.

G. Conflict of Interest Policy Implementation for Grants Selection

The Conflict of Interest Policy Implementation for Grants Selection minimizes the potential for bias in awarding Society- and CCF-supported research grants by setting standards for disclosure and recusal by grant reviewers.

H. Conflict of Interest Implementation for Quality Oncology Practice Initiative Certification

The Conflict of Interest Implementation for the Quality Oncology Practice Initiative (QOPI) Certification Program provides criteria for the selection and recusal of reviewers and auditors for the certification, appeal, waiver, and recertification processes.

I. Fundraising

It is ASCO’s policy and practice to carry out fundraising activities in compliance with the Society’s and CCF’s mission and tax-exempt status, and to separate fundraising activities, which are conducted by CCF, from development of Society programs and budgets.

IV. MANAGEMENT OF POTENTIAL CONFLICTS OF INTEREST

Information disclosed under this Policy will be used to identify and manage potential conflicts of interest, in accordance with the Implementations Plans and procedures described in section II, as well as through longstanding ASCO, JCO, and JOP practices of disclosure and rigorous peer review.

V. RESTRICTIONS ON CERTAIN RELATIONSHIPS

This Policy calls for disclosure and management of financial relationships with Companies and does not create a presumption of impropriety in the existence of these relationships. 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. Individuals who are free of these relationships should play a key role in the authorship of original research submitted to ASCO meetings or to JCO and JOP. Although the contribution of every author is important, ASCO looks to these individuals primarily to ensure the balance and objectivity of the research as presented.

A. Original Research in ASCO Educational or Scientific Programs

Abstracts and articles concerning original research are not eligible for inclusion in an ASCO educational or scientific program if the first, last, or corresponding author has:

1. participated in a speakers’ bureau (on any subject) on behalf of the Company sponsor of that original research at any time during the 2 years before submission of the abstract;
2. held an employment relationship with the Company sponsor of that original research at any time during the 2 years before submission of the abstract; or
3. held a significant ownership interest (as defined in this Policy; see Glossary) in the Company sponsor of that original research at any time during the 2 years before submission of the abstract.

B. Original Research in ASCO Journals

Manuscripts (including articles and abstracts) concerning original research are not eligible for publication in JCO or JOP if the first, last, or corresponding author has:
1. participated in a speakers’ bureau (on any subject) on behalf of the Company sponsor of that research at any time during the 2 years before submission of the manuscript;
2. held an employment relationship with the Company sponsor of that research at any time during the 2 years before submission of the manuscript; or
3. held a significant ownership interest (as defined in this Policy; see Glossary) in the Company sponsor of that research at any time during the 2 years before submission of the manuscript.

C. Exemption for Certain Articles in JOP

The eligibility restrictions set out in Section V(b) do not apply to JOP manuscripts that primarily involve clinical practice efficiency or clinical and administrative management. Such articles are subject to disclosure, peer review, and editorial management by JOP as appropriate.

D. Exemption for Research Sponsored by the National Institutes of Health

Original research sponsored in whole or in part by the National Institutes of Health (“NIH”) is not subject to the restrictions set out in Section V(a) and (b), because NIH-sponsored trials feature sufficient safeguards to ensure objectivity and independent review of safety and other data developed in the research.

E. Other Restrictions

Additional restrictions on the relationships held by ASCO leaders, volunteers, and presenters are set out in the Implementation Plans described in Section II.

VI. EFFECTIVE DATE OF POLICY

This policy is effective on the date of online publication, April 22, 2013, with the exception of the author restrictions set out in Section V. The restrictions set out in Section V will go into effect 1 year from the date of online publication of this Policy (ie, author restrictions will take effect after April 22, 2014) and will only apply to original research that is initiated after that date. ASCO will rely on the judgment and integrity of investigators to determine when original research is initiated. For clinical trial reports, the date of research initiation will generally be the date of the first patient accrual. For original research that constitutes a clinical trial initiated before April 22, 2014, the 2005 ASCO Conflict of Interest Policy as it relates to principal investigator relationships (Section VII of 2005 Policy) will remain in effect through a transition period as determined by ASCO. In such cases, restricted financial relationships will be disclosed and managed in accordance with the 2005 Policy and ASCO procedures.

VII. ENFORCEMENT OF POLICY

Covered individuals who do not comply with the requirements of this Policy or applicable Implementation Plans or procedures may face sanctions under the ASCO Member Discipline Procedures, any ASCO Author Conduct Policy, and the Conflict of Interest Implementation Plan for CME Activities, as applicable. Sanctions may include but are not limited to:
1. exclusion from submitting abstracts or presenting at Society CME activities;
2. exclusion from publishing in ASCO publications;
3. exclusion or removal from participation on ASCO committees, editorial boards, clinical practice guideline panels, and other volunteer positions; and
4. censure, suspension, or revocation of ASCO membership.

VIII. GLOSSARY

Terms used in this Policy are defined below:
"Clinical practice guideline" is defined in the CMSS Code as "a systematically developed statement to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances." (For a more detailed definition, see http://www.cmss.org/codexforinteractions.aspx.)
"Company" is defined in the CMSS Code as "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. This definition is not intended to include non-profit entities, entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients" (see http://www.cmss.org/codexforinteractions.aspx).
"Immediate family member" means spouse, dependent child, or other person with whom a covered individual shares income or assets and believes disclosure is relevant.
"Management" means any of a range of actions intended to respond to an actual, potential, or perceived conflict of interest. In some cases, disclosure of relevant financial relationships is sufficient for management. Other examples of conflict of interest management include recusal from decision making, peer review, use of a discussant, and audit of CME sessions. As suggested in the CMSS Code, ASCO will employ conflict of interest management mechanisms that are appropriate for the activity and type of relationship under consideration.
"Original research" means a systematic investigation designed for the purpose of expanding knowledge or understanding, including the analysis of data. For clarity, a clinical trial is original research under this definition, and a summary or review of prior knowledge is not original research under this definition.
“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 submission. This does not include interests invested in diversified funds with holdings that cannot be controlled by the disclosing individual. This definition may be updated by ASCO from time to time in a published “FAQ” or other communication.

“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.

**AUTHOR’S DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**

The author(s) indicated no potential conflicts of interest.

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**REFERENCES**


On January 13, 2014, the ASCO Board of Directors adopted a change to the Policy for Relationships with Companies, which was published online on April 22, 2013 (J Clin Oncol 31:2043-2046, 2013). Section VI of the Policy is replaced with the following: “This policy is effective on the date of online publication, April 22, 2013, with the exception of the author restrictions set out in Section V. ASCO will not enforce the restrictions set out in Section V until after a period of data-gathering and analysis that will continue at least through April 22, 2016. Financial relationships of first, last, and corresponding authors will be disclosed and managed in accordance with ASCO procedures. Any future enforcement of the author restrictions will be prospective (ie, will only apply to research initiated after the restrictions go into effect). The 2005 ASCO Conflict of Interest Policy (including policies relating to principal investigator relationships in Section VII of the 2005 Policy) expired as of January 13, 2014 and is no longer in effect.”