

**POLICY FOR MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST IN THE
DEVELOPMENT OF ATS CLINICAL PRACTICE GUIDELINES**

PURPOSE

Within the past ten years, the American Thoracic Society (ATS) has taken several steps to strengthen the disclosure and management of conflicts of interest (COI) of clinical practice guideline panel members, with particular attention to the actual, perceived and/or potential COI caused by financial interests relevant to guideline subject matter. The steps are described in detail in the appendix at the end of this document. This policy provides an approach to managing COI in the development of ATS clinical practice guidelines that is consistent with the expectations of the guideline development community, health care professionals and public, including the need to maximize consideration of evidence and expert opinions in a manner that ensures independent analysis, independent decision-making, and high confidence in guideline quality and integrity.

REQUIREMENTS

A. DISCLOSURE

To whom: All individuals who are invited to participate in a guideline development panel must disclose to the ATS all COI and, if the guideline is co-sponsored by another society, to that society if requested. Approved panelists must also disclose their COI to the other panel members at the beginning of each meeting.

Panelists must allow the ATS to review their declared COI and determine whether or not these conflicts are manageable for the particular panel and, if manageable, how they should be managed.

When: Disclosures must be made prior to the commencement of guideline development and then updated annually. If a potential COI arises during guideline development, it must be disclosed immediately. It is advised that approved panelists consult the ATS COI management staff prior to engaging in any activity that may result in a COI related to guideline development.

What: Panelists must disclose the following relationships if held by them or their life partner at the time they are invited to participate on the guideline panel or if held during the preceding three years:

- A. Professional or financial relationships with tobacco or e-cigarette entities.
- B. Professional or financial relationships with a company known to have a business interest in the subject matter of the guideline.
- C. Ownership of intellectual property (including patents or patents pending) that is related to guideline content.
- D. If a potential recommendation of the guideline would jeopardize or enhance the panelist's professional work or professional group fundamentally (definition of intellectual conflict of interest of the Institute of Medicine, National Academy of Sciences, *Clinical Practice Guidelines We Can Trust*, 2011). For example: if the

panelist runs a laboratory that performs a diagnostic test that may be directly recommended for or against by the guideline; if the panelist is director of a simulation center and a recommendation may be made for or against simulation-based training.

2. REVIEW AND CATEGORIZATION OF CONFLICTS OF INTEREST

The COI disclosures of individuals who are invited to participate in an ATS guideline development panel are reviewed by staff from the ATS COI management unit and ATS documents unit prior to the individual being accepted as a panel member. The ATS Ethics and Conflict of Interest Committee and the Documents Development and Implementation Committee will provide oversight and advice as needed.

Based upon their disclosures, proposed panelists are considered as either free from relevant COI, having manageable COI that require management, or having disqualifying COI that must be terminated in order to serve as a member of the guideline panel. Experts in the subject matter of the guideline that have disqualifying COI may be permitted by the ATS to participate as a non-voting expert contributor.

No Relevant Conflicts of Interest: Individuals with no relevant COI are approved for full participation. Research funding that is free of direct or indirect industry funding or control, such as that provided by a government program or a non-profit organization that does not receive industry funding and uses an award mechanism and oversight that is independent of industry, is not regarded to be a conflict of interest. Service on a data and safety monitoring board for such research is also not regarded as a conflict of interest. Individuals classified as without relevant COI may participate in determining the scope and health care questions to be addressed in the guidelines, review and discuss the evidence, formulate and grade recommendations, vote on recommendations, and write the document.

Manageable Conflicts of Interest: Manageable conflicts of interest that require management include:

- A. Research funding from an industry grant that is paid to the participant's institution and related to the content of the guideline;
- B. Research funding from a government program or non-profit organization that receives funding from industry with business interests in the content of the guideline;
- C. Participation on a data and safety monitoring board concerned with research that is relevant to the content of the guideline and is funded by an industry with business interests in the content of the guideline, or by a government program or non-profit organization that receives funding from industry with business interests in the content of the guideline.
- D. Participation in industry-funded research, scientific advisory committees, consulting roles, non-promotional speaking engagements, or expert testimony on matters that

- are unrelated to guideline subject matter but the company involved is known to have business interest in the guideline subject matter;
- E. Delivery of non-promotional talks in which the speaker has full control of the content and is either unpaid or paid by a third party that is responsible for ensuring that the event is free of influence of relevant industry (i.e. if the event has industry financial support, all planning and content must be free of industry influence, and any payment of expenses and honoraria must occur through a third party, such as the medical society or institution sponsoring the event, or an event manager acceptable to them, rather than directly by a commercial entity with an interest in guideline subject matter or its agent);
 - F. If a potential recommendation of the guideline would jeopardize or enhance the panelist's professional work or professional group fundamentally (definition of intellectual conflict of interest of the Institute of Medicine, National Academy of Sciences, *Clinical Practice Guidelines We Can Trust*, 2011).

Individuals with manageable conflicts must disclose their conflicts to the whole guideline panel. Individuals with manageable conflicts as defined in categories A. through E. above will be permitted to participate in discussions about the evidence, but must excuse themselves or be recused from decision making, including formulating, voting on, writing, and grading recommendations related to their conflict of interest (i.e., recommendations addressing a product of the commercial entity with which they have a relationship or addressing a product of a competitor of the commercial entity with which they have a relationship). Individuals with a manageable conflict as defined in category F. above will be permitted to participate in discussions about the evidence, but must attest that the intellectual conflict will not bias their participation in the panel, and may be required by the ATS to excuse themselves or be recused from decision making on relevant recommendations if the ATS thinks that there is a high likelihood that guideline readers would regard the individual's direct participation in decision-making on the relevant recommendation as lessening reader confidence that the recommendation was developed in a manner independent of any financial or intellectual consequences for panelists. Determination of the need for excusal or recusal of panelists with a manageable conflict as defined in category F. above will be made by the ATS Documents Editor in consultation with ATS COI management staff, the leadership of the ATS Documents Development and Implementation Committee, and the ATS Executive Committee.

It is the responsibility of guideline panel (co-)chairs to ensure that individuals with manageable conflicts are excused or recused as described above. Chairs will be advised by ATS staff in managing panel members with manageable conflicts of interest, and in summarizing management actions for ATS and within the methods section of the guideline.

Disqualifying Conflicts of Interest: COI that cause disqualification for membership on an ATS guideline panel include:

- A. In keeping with the ATS policy on tobacco industry relationships, a current professional relationship with or investment in a company involved in the manufacture or distribution of tobacco products.

- B. A direct financial relationship with a commercial entity that has an interest in the content of the guideline (a “relevant company”), exclusive of the research and data and safety monitoring board activities noted above. Such direct financial relationships include the following, whether paid to or held by the individual directly or issued to another entity at the direction of the individual (such as to a panelist’s institution):
 - i. Payment of wages, consulting fees, honoraria, or other payments (in cash, in stock or stock options, or in kind) by a relevant company as compensation for the individual’s services or expertise, exclusive of the research and data and safety monitoring board activities noted above. Examples of such services are: participation on relevant scientific advisory committees; consulting; non-CME speaking engagements and inclusion in speaker bureaus; expert testimony on matters related to guideline content provided on behalf of a relevant company or a law firm representing a relevant company; employment by a relevant commercial entity (such as a relevant pharmaceutical or medical device company or a third party payer that has financial interests in guideline content).
 - ii. Investments in relevant companies by the panelist or the panelist’s spouse or life partner (exclusive of general mutual funds).
- C. A patent or other intellectual property that is relevant to the guideline’s subject matter and has resulted or could result in payments to the panelist or the panelist’s institution.

Proposed panelists with disqualifying COI will be notified by staff of the ATS COI management unit. The disqualified panelist may be permitted to serve if the disqualifying relationship is terminated prior to when the panel begins its work. Permission requires consideration of the matter by ATS COI management and documents unit staff, and assurance by the proposed panelist that ATS requirements for remediation of the disqualifying relationship will be met. These requirements include:

- A. Termination of the COI as far in advance of panel activity as possible to avoid any appearance of influence on panel participation, and
- B. The panelist must refrain from disqualifying relationships throughout the period of guideline development and for a period of at least one year following publication of the guideline.
- C. Disqualifying relationships that are terminated prior to when the panel begins work, in order to allow panel participation, must also be disclosed to the ATS and panel members and treated as a manageable conflict that requires appropriate management, including recusal from decision-making on recommendations that address a product of the commercial entity with which the panelist had the disqualifying relationship, or a product of a competitor of the commercial entity with which he or she had the disqualifying relationship. The existence of the relationship will also be reported within the author disclosures that accompany the guideline when published.

Non-voting Expert Contributors*: ATS recognizes that experts in the subject matter of a guideline may be unable to serve as ATS guideline panelists due to financial relationships that cause disqualification. These experts often possess unique insight into guideline-relevant content and their observations may provide valuable insight into a topic. For example, the experts may be aware of relevant information about study design and conduct that is not easily identified in published articles. Proposed panelists with disqualifying COI who decline to terminate their disqualifying relationship(s) cannot become panel members; however, they may be permitted by ATS to participate as “non-voting expert contributors” to the guideline. They may participate in discussions of the evidence related to their specific expertise, but may not participate in discussions about any recommendations, regardless of whether the recommendations are related to their disqualifying relationship. Non-voting expert contributors must meet all ATS disclosure requirements (as stated earlier for panelists), and be approved by ATS documents unit staff, prior to any participation. Employees of commercial entities may not serve as non-voting expert contributors.

3. GUIDELINE DEVELOPMENT PANEL COMPOSITION

The chair (if only one) or the majority (i.e. >50%) of co-chairs and the majority of guideline development panel members must be free from relevant conflicts of interest. The majority threshold is meant to be the minimal acceptable standard; guideline development panels should strive to maintain as large a proportion of individuals free from relevant COI as possible, while maintaining the necessary expertise to develop the guidelines.

4. OTHER REQUIREMENTS

Confidentiality: All discussions and work by the guideline development panel must remain strictly confidential. Every member of a guideline development panel will be required to sign a confidentiality agreement to participate in the project. The confidentiality requirement begins the moment that an individual is accepted onto the guideline development panel and continues until the document is formally approved by the ATS Board of Directors. This includes discussions with co-workers, colleagues, and other ATS members. In addition, consistent with the expectation that clinical practice guidelines be developed in a manner that is independent of business interests, panelists are not permitted to discuss a guideline’s development with employees or representatives of the entities with vested interest in guideline subject matter. Guideline panels may not accept unpublished data from industry. Guideline panel members will not permit individuals employed by industry or acting on behalf of industry to review guidelines in draft form. Potential penalties for violating the confidentiality agreement include the following:

- A. Immediate removal from the guideline development panel;
- B. Elimination of any opportunities for authorship associated with the guideline;
- C. Disqualification from participation in any future ATS clinical practice guidelines or other official documents;

* This role is being piloted by guideline projects that commence between January 1, 2017 and December 31, 2017, as approved by the Board of Directors on December 8, 2016.

- D. Termination of the panel member's membership in the ATS. In addition, the co-sponsoring societies will be informed of the breach.

Publication of disclosures: All relevant COI of guideline panel members that were in existence during guideline development and the previous three years, and known by ATS, will be published together with the ATS clinical practice guideline. All ATS guideline documents should include a Methods section describing in sufficient detail the processes used to identify and manage conflicts of interest during guideline development. In addition, each ATS guideline should describe the decision-making process, instances of substantial disagreement, reasons for that disagreement, the need for voting, and the results of voting, if used.

Speaking related to the guideline topic: All guideline panel members, irrespective of conflicts of interest, should refrain from speaking activities related to the guideline's subject matter that involve payments by industry directly to the speaker during the period of guideline development and for one year after publication. Panelists should also decline offers to speak about the guideline on behalf of an entity with an actual, perceived, and/or potential vested interest in guideline subject matter for a reasonable period (at least one year is recommended) after guideline publication. An affected company is one that is reasonably likely to be positively or negatively affected by care delivered in accordance with the guideline.

5. COLLABORATION WITH OTHER ORGANIZATIONS

Implementation of this policy may be modified for joint guideline development with organizations whose conflict of interest policies differ from that of the ATS only if the importance of the collaborative guideline justifies departing from ATS policy. In those cases, a good faith effort should be made to persuade the other societies to adopt ATS standards. Prior to convening the guideline development panel, a memorandum of understanding (MOU) must be developed and signed by the participating organizations that explicitly describes the rules for managing conflicts of interest as agreed upon by the co-sponsoring organizations. Conformance with ATS core values, ATS COI policies, and the Council of Medical Specialty Societies (CMSS) *Code for Interaction with Companies* (where endorsed by the ATS) should be sought to the fullest extent possible. The final agreement on COI must include recusal of those with manageable COI from decision-making (formulating, writing, and grading recommendations) as a minimal standard and must be consistent with the development of a final product that is not compromised by COI among any of the participants.

6. FAILURE TO DISCLOSE

Any guideline panel member who is suspected of having failed to disclose a relevant COI at the time of disclosure to the ATS or having failed to disclose to the ATS a new COI acquired during the time since he or she was appointed to the panel will be contacted by the staff of the ATS COI Management unit and asked to update their disclosures. Previously undisclosed COI that are confirmed will be categorized as manageable or disqualifying as described above. The panel member will be permitted to remain on the panel if the COI is regarded by the ATS as a manageable COI, but will need to either resign from the panel or be permitted by the ATS to

immediately discontinue the pertinent relationship if the COI is regarded by the ATS as a disqualifying COI. In either case, any matters in which the panelist participated in decision-making related to their conflict of interest will need to be reconsidered, including formulating, writing, voting on, and grading recommendations. In keeping with the ATS policy on professionalism and ethical conduct, failure to disclose COI in a manner that appears to the ATS to be deliberate rather than inadvertent may result in penalties that could include the following:

- A. Immediate removal from the guideline development panel;
- B. Elimination of any opportunities for authorship associated with the guideline;
- C. Disqualification from participation in any future ATS clinical practice guidelines or other official ATS activities ;
- D. Termination of the panel member's membership in the ATS.

In addition, the co-sponsoring societies will be informed of the breach. Undisclosed COI that are discovered following publication will necessitate publication of an erratum that describes the failed disclosure.

ATS STAFF RESOURCES

Shane McDermott, Senior Director, Ethics and Conflict of Interest Management (smcdermott@thoracic.org).

Kevin Wilson, MD, Chief, Documents and Medical Affairs (kwilson@thoracic.org).

Jan Brozek, MD, PhD, Methodologist (brozekj@mcmaster.ca).

John Harmon, Manager, Document Development and COI Management (jharmon@thoracic.org).

Judy Corn, Director, Documents and Patient Education (jcorn@thoracic.org).

APPENDIX: BACKGROUND

1. In 2000, the ATS Board of Directors discontinued the acceptance of pharmaceutical company funding support for the development of ATS clinical practice guidelines, as a means of further assuring that clinical recommendations are independent of any business interests.
2. In 2006, the ATS began to require guideline authors to fully disclose all potential conflicts of interests relevant to subject matter, and began to include a summary of relevant disclosures within the published document.
3. In 2007, the ATS Board of Directors enacted a *Policy Governing Relationships Between the Tobacco Industry, ATS Members, and Non-Members Who Participate in ATS Activities* that prohibits individuals with a current relationship with a tobacco entity, or one within the past twelve months, from holding various official ATS roles, including service on a writing committee of an ATS statement or guideline. (The ATS subsequently added disclosure of involvement with e-cigarette entities as a requirement, but does not currently regard that as a disqualifying relationship.)

4. In 2008, the Board of Directors enacted a *Policy on Management of Conflict of Interest in Official ATS Documents, Projects and Conferences*. The policy stated that: “Conscious or subconscious influence as a result of COI, or the perception by others that such influence exists, may impact the balance of considerations within institutions and organizations in favor of a particular management option. ... Scientific organizations like the ATS possess a credibility among clinicians, scientists and laypersons that is tied directly to the integrity of its conduct. COI have the potential to compromise the validity of ATS activities.”
5. The 2008 policy specified that the following be required, in addition to the requirements noted above:
 - Chairs and organizers of official ATS activities should evaluate the COI disclosures of potential participants and take steps as recommended by the ATS to resolve relevant conflicts of interest.
 - Chairs and panelists should ensure that committees are reminded of the specific COI before discussion of individual conclusions or recommendations on which those COI bear. If the COI are not resolved, participants should recuse themselves, or chairs should excuse the participants, from discussions or decision-making on particular recommendations.
 - COI should be published with all ATS-sanctioned documents ... and reference should be made to the policies (herein described) and processes used to identify and resolve COI during [the project’s] development. For example, for official ATS documents this includes stating the evidence and the decision-making process, and labeling instances of substantial disagreement and the reasons for that disagreement, in printed documents.
6. In 2012, the Board of Directors adopted the Council of Medical Specialty Societies’ *Code for Interactions with Companies*, which among other provisions included specific requirements for clinical practice guidelines. Several provisions affirmed the previously-enacted ATS requirements, including that clinical practice guidelines cannot be funded by companies (inclusive of initial printing, publication, and distribution), and all potential conflicts of interest must be disclosed by Guideline development panel members. In addition, the Code required that:
 - “A majority of panel members be free of COI relevant to the subject of the guideline;”
 - “At least one co-chair be free of COI relevant to the subject of the guideline and remain so for at least one year after publication. “
 - “Societies will recommend that guideline development panel members decline offers from affected companies to speak about the guideline on behalf of the Company for a reasonable period after publication. (Annotation: A period of at least one year is recommended. An affected company is one that is reasonably likely to be positively or negatively affected by care delivered in accordance with the Guideline.)”
 - “Societies will not permit Guideline development panel members or staff to discuss a Guideline’s development with Company employees or representatives, will not accept unpublished data from Companies, and will not permit Companies to review Guidelines in draft form.”

7. External expectations of clinical practice guidelines developed by medical societies in North America have continued to evolve. For example, recommendations on guideline development have been issued by the Institute of Medicine, the Guidelines International Network, and the National Guidelines Clearinghouse. External expectations have become more rigorous, including in regard to management of COI. Guideline developers are increasingly expected to not only disclose conflicts, have a majority of panelists without relevant conflicts, and require that panelists with conflicts recuse from relevant decisions, but also when forming panels distinguish between “manageable conflicts” that can be managed and “disqualifying conflicts” that must be terminated to serve on a guideline panel.