

American Thoracic Society Documents

An Official American Thoracic Society Policy Statement: Managing Conflict of Interest in Professional Societies

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THIS OFFICIAL POLICY STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS APPROVED BY THE ATS BOARD OF DIRECTORS ON MAY 20, 2009.

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Background: Competing interests occur frequently in health care. This results in the potential for conflict of interest (COI). COI can lead to biased generation or assessment of evidence and misinform healthcare decision makers. Declaration of COI is insufficient to neutralize potentially harmful effects. Medical professional societies are obliged to develop robust mechanisms to “manage” COI, particularly in the development of official guidance documents that affect health care.

Purpose: This document describes the background, methods, and content of the new “American Thoracic Society (ATS) Policy on Management of COI in Official ATS Documents, Projects, and Conferences.”

Methods: We used existing reviews on COI policies that were prepared for the World Health Organization and for an ATS guideline methodology workshop as the evidence base for this work. We reviewed existing policies of selected organizations and other relevant literature. Members of the ATS Documents Development and Implementation Committee and the ATS Ethics and COI Committee collaborated to draft a COI policy. We used face-to-face meetings, electronic correspondence, and teleconferences to finalize the draft. The policy then underwent review and ultimate approval by the ATS Board of Directors.

Results: The ATS developed a new policy and procedures for declaration and management of COI. These procedures include: (1) self declaration of COI, (2) review of potential participants’ COI, (3) disclosure of COI to

project participants, (4) recusal or excusal from certain decisions or recommendations when appropriate, (5) disclosure of COI to users of documents or attendees of conferences, (6) handling disputes in COI resolution. This policy includes a tool that may be useful for supporting decision makers in management of COIs as they assess the value and relevance of conflicts.

Conclusions: The ATS Policy on Management of COI in Official ATS Documents, Projects, and Conferences, in effect since March 2008, promises greater organizational transparency. Application and ongoing evaluation of the policy will give the ATS the opportunity to determine its usefulness in specific settings.

EXECUTIVE SUMMARY

Introduction: Competing interests occur frequently in health care. This results in the potential for conflict of interest (COI). COI can lead to biased generation or assessment of evidence and misinform health care decision makers. Declaration of COI is insufficient to neutralize potentially harmful effects. Medical professional societies are obliged to develop robust mechanisms to “manage” COI, particularly in the development of guidance documents. This document describes the background, methods, and content of the new American Thoracic Society (ATS) Policy on Management of COI in Official ATS Documents, Projects and Conferences. In 2006, ATS leadership charged the Documents Development and Implementation Committees and the Ethics and Conflicts of Interest Committee to develop a comprehensive policy to address COI management for ATS activities and derivatives.

Methods: We used existing reviews on COI policies that were prepared for the World Health Organization and for an ATS guideline methodology workshop as the evidence base for this policy and reviewed existing policies of the following selected organizations: American College of Physicians (ACP), American College of Chest Physicians (ACCP), American Medical Association (AMA), Society of Critical Care Medicine (SCCM), International Committee of Medical Journal Editors (ICMJE), World Health Organization (WHO). Members of the ATS Documents Development and Implementation Committee, and the ATS Ethics and COI Committee prepared drafts of a COI policy. The policy was approved by the ATS Board of Directors, March 14, 2008 and amended May 14, 2008.

Supported by ATS funds.

Am J Respir Crit Care Med Vol 180. pp 564–580, 2009
DOI: 10.1164/rccm.200901-0126ST
Internet address: www.atsjournals.org

Goals: The two main goals of the policy are (1) to enhance the objectivity, scientific rigor, and transparency of official ATS activities by providing an explicit methodology regarding COI for individuals who prepare an official ATS document (statement), or participate in a project, conference, or other official ATS activity, and to identify and disclose all personal or institutional “competing interests” that may cause or be perceived as causing a COI affecting the individual’s participation in the activity, and to resolve all COIs; and (2) to provide a mechanism for disclosure and resolution of conflicts of interest in a manner that is respectful of the ATS members and other individuals essential to ATS activities.

Principles: The policy is based on eight principles that are summarized in Table 1. These principles encompass (1) the recognition that the ATS membership is diverse with work affiliations ranging from academic institutions, industry, patient care, government, research, to administration; (2) individuals employed or directly affiliated with the pharmaceutical and/or medical device industry make important and often unique contributions to official ATS activities; (3) 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. Since the ATS is likely to affect health care, public health, and health policy proportional to its credibility, the ATS must preserve its organizational integrity and rigorously safeguard its processes to disclose and resolve COI; (4) many individuals have “competing interests” that may cause conflicts of interest. A conflict of interest depends on the situation, and not on the character or actions of the individual; (5) simple *a priori* declaration of COI is insufficient; (6) 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 COI; (7) project committee members and/or conference or workshop participants should be apprised of the declared COI of all other participants before deliberations begin; (8) COI should be acknowledged in final published documents or other products of the project or conference, with footnotes that allow users of the document or other products to access and assess the policies that safeguarded COI during the project or conference’s development.

Definitions: COI is defined as (1) a divergence between an individual’s private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual’s professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams or community standing; or (2) a financial or intellectual relationship that may impact an individual’s ability to approach a scientific question with an open mind.

TABLE 1. PRINCIPLES FOR THE POLICY

1. Diversity in the ATS membership is valued.
2. All ATS members make unique and valuable contributions to official ATS activities.
3. Influence as a result of COI or even perception of COI can impact the balance of considerations in favor of a particular management option.
4. Although competing interests may cause COI, this depends on the situation rather than the character or actions of individuals.
5. Simple declaration of COI is insufficient.
6. 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 COIs.
7. Project committee members and/or conference or workshop participants should be apprised of the declared COI of all other participants before deliberations begin.
8. COI must be acknowledged in the final document or other product of a project or conference.

Procedures: The following process should be used to identify and resolve COI for individuals involved in official ATS activities.

1. Self declaration of COI: all participants in official ATS activities should submit written disclosures of all competing interests that may cause a conflict of interest for them in carrying out an official ATS activity, including employment by a commercial entity, consultancy, board or advisory board membership, lecture fees, expert witness income, industry-sponsored grants including contracted research, patents received or pending, royalties, stock ownership or options, other personal financial interests. The disclosure statement should also include: noncommercial interests that are relevant or potentially relevant to official activities of the ATS; whether the institution or employer has a financial relationship with a commercial entity that has an interest in official activities of the ATS (the individual is not required to make specific inquiries of the authorities of his/her institution).
2. Review of potential participants’ COIs: those choosing participants for official ATS activities should review disclosures before deciding on participants, and exclude participants if there is a non-resolvable conflict of interest.
3. Disclosure of COIs to project participants: once the members of a project committee have been assembled, COIs of members should be identified and discussed before beginning deliberations. Individual participants (including project chairs and panelists) should label where COIs bear on specific recommendations in documents.
4. Recusal or excusal from certain decisions or recommendations when appropriate: chairs and panelists should ensure that committees are reminded of the specific COIs before discussion of individual conclusions or recommendations on which those COIs bear. If the COIs are not resolved, participants should recuse themselves, or chairs should excuse the participants, from discussions or decision-making on particular recommendations.
5. Disclosure of COI to users of documents or attendees of conferences: COIs in official ATS activities should be minimized and transparent. ATS policies for COI disclosure and resolution should be publicly available for all users of ATS documents and attendees of ATS conferences.
6. Handling disputes in COI resolution: The ATS Ethics and COI Committee should develop and oversee the procedures and instruments used to disclose, review, and resolve COI, and should advise and assist chairs and organizers where necessary.

Conclusions: Individuals with expertise in specific areas of healthcare often have potential COIs, sometimes as a result of their usual professional activity. However, such COIs require management to reduce the possibility of influence on healthcare policy and decisions. The ATS Policy on Management of COI in Official ATS Documents, Projects and Conferences promises greater transparency in the declaration and management of potential COIs. It also includes considerations about non-monetary COIs including potential academic conflicts. Ongoing evaluation of the policy will inform the ATS about its usefulness in specific settings.

INTRODUCTION

COI can lead to biased generation or assessment of evidence and misinform healthcare decision makers (1, 2). Declaration and management of COI is therefore of increasing importance for medical professional societies and other organizations (3–10).

This document describes the background, methods, and content of the ATS Policy on Management of COI in Official ATS Documents, Projects, and Conferences.

METHODS

We used an existing review on COI policies that was prepared for the World Health Organization as evidence base for this policy and for an ATS guideline methodology workshop (3, 11). We supplemented this work by a review of existing policies of the following selected organizations (*see* APPENDIX 4): ACP, ACCP, AMA, SCCM, ICMJE, WHO. We also included other relevant literature known to members of the writing committee. Members of the ATS Documents Development and Implementation Committee and the ATS Ethics and COI Committee prepared drafts of a COI policy. We used face-to-face meetings, electronic correspondence, and teleconferences to finalize the draft. The policy was then submitted to the ATS Board of Directors for review and approval.

THE POLICY

The following text represents the official wording of the resulting ATS policy on "Management of conflict of interest in official ATS documents, projects, and conferences" as approved by the ATS Board of Directors, March 14, 2008 and amended May 14, 2008.

I. INTRODUCTION TO THE POLICY

The purpose of this document is to establish a fair and transparent framework for individuals with conflicts of interest to continue to participate as valued members or partners of the Society. This document is a result of a review, analysis, and discussion of existing COI documents, policies, and procedures of the ATS and other professional organizations (*see* APPENDICES 3, 4, and 5). It was prepared by an *ad hoc* committee of the ATS Ethics and Conflict of Interest Committee, the ATS Documents Development and Implementation Committee, and ATS staff.

II. GOALS OF THE POLICY

1. To enhance the objectivity, scientific rigor and transparency of official ATS activities by providing an explicit methodology regarding COI for individuals who prepare an official ATS document (statement), or participate in a project, conference or other official ATS activity, to (a) identify and disclose all personal or institutional "competing interests" that may cause or be perceived as causing a "conflict of interest" (COI) affecting the individual's participation in the activity, and (b) resolve all conflicts of interest (12).
2. To provide for disclosure and resolution of conflicts of interest in a manner that is respectful of the ATS members and other individuals essential to ATS activities, and respectful of confidentiality to the extent appropriate.

III. PRINCIPLES

1. The ATS membership is diverse. ATS members can have their primary work affiliations in academic institutions, industry, patient care, government, research, and administration. Regardless of affiliation, the ATS values the contributions of all of its members and affirms the value of different experiences and points of view. Because of the diversity of our members' affiliations, their interests may compete with the interests of the ATS and represent a conflict of interest when participating in ATS activities.
2. Physicians and scientists employed or directly affiliated with the pharmaceutical and/or medical device industry make important

and often unique contributions to official ATS activities. Researchers and "content experts" are often involved in activities on behalf of professional organizations. In many cases, these same experts receive industry funding to consult, lecture, participate in industry scientific advisory boards, conduct research, or provide other services (13). Some researchers and content experts or their institutions have proprietary interests in a substance, technology, or process that has resulted from their work. Some experts serve as paid witnesses in legal proceedings or as consultants in litigation. Practicing clinicians can be involved in activities such as clinical research studies and public speaking that can affect revenue streams and community standing. Such relationships produce COI that may compete with activities performed on behalf of a professional organization (14). As they are directly involved in commercial goals by the nature of their existence, disclosure of such involvements must be transparent and be guided by the highest ethical standards and codes of conduct.

3. 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 (15). This topic as it relates to guideline development has been the subject of a recent review by Boyd and Bero (11). 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. Since the ATS is likely to affect health care, public health, and health policy proportional to its credibility, the ATS must preserve its organizational integrity and rigorously safeguard its processes to disclose and resolve COI.

4. Many individuals have "competing interests" that may cause conflicts of interest. A conflict of interest depends on the situation, and not on the character or actions of the individual.

5. Simple *a priori* declaration of COI is insufficient.

6. 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 (*see* SAMPLE GUIDELINES, APPENDIX 3). They may require more information to better assess and resolve COI. If necessary, the ATS Board of Directors and the Ethics and Conflict of Interest Committee should at their discretion have the opportunity to review these decisions before final assignments to official ATS activities are made.

7. Project committee members and/or conference or workshop participants should be apprised of the declared COI of all other participants before deliberations begin. Fellow participants become one "check" to resolve COI throughout the process of project and conference development and implementation.

8. COI should be acknowledged in the final published document or other products of the project or conference, with footnotes that allow users of the document or other products to access the policies that safeguarded COI during the project or conference's development.

IV. DEFINITIONS

1. **Conflict of interest (COI)** will be defined as:

- a. A divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing.

b. A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind. Examples:

i. All financial relationships including employment, consultancies, known stock holdings or holdings in a sector fund relevant to the subject matter, honoraria, in-kind gifts or benefits, endowments, patents, royalties, and paid expert testimony. Examples of in-kind gifts or benefits are travel, accommodation, meals, or frequent flier miles.

ii. Personal, intellectual, or academic relationships that interfere with an individual's ability to consider or interpret the full breadth of available data or alternative points of view objectively. Examples include inability to review a grant, manuscript, or project proposal objectively due to competition for funding, timing of publication, or professional stature.

2. **“Official ATS activities”** here refers to the development of official ATS documents, participation in any projects or conferences, and serving the Society in an official capacity.

3. **“Participants”** in official ATS activities here include members of the ATS Board of Directors; ATS standing and *ad hoc* committees and task forces; Assembly leadership; the members of writing committees and/or organizing committees for official ATS projects; the chairs, organizers, and/or presenters or panelists at official ATS conferences and workshops; and ATS staff.

4. **“Commercial entity,” “company,” or “industry”** here refers to manufacturers of devices, drugs, or other products used in health care or scientific research in which participants in ATS activities are involved, and/or manufacturers of products or processes that are thought to cause respiratory disease or disorders.

V. PROCEDURES

The following process should be used to identify and resolve COI for individuals involved in official ATS activities:

1. SELF-DECLARATION OF COI:

a. All participants in official ATS activities should submit written disclosures of all competing interests that may cause a conflict of interest for them in carrying out an official ATS activity. Disclosures should be made *prior* to being involved in an official capacity (i.e., after the invitation or application to participate in an official ATS activity is made, but before becoming an official participant). The individual should declare in writing: all known current and past interests relevant to the subject and scope of the matter for the period of 3 years prior to the date of declaration; and any conflicts of interest relevant to the subject and scope of the matter that are expected to occur in the near future.

b. All reviewers of grants or manuscripts should disclose any competing interests to committee chairs or editors, respectively.

c. Disclosure should be made through a standard ATS form and uniform online process approved by the ATS Ethics and Conflict of Interest Committee (see APPENDIX 1). All participants in official ATS activities should be asked to complete a disclosure form, update it as individual circumstances warrant, and attest to its accuracy and currency when requested by the ATS.

The disclosure statement should include:

i. DISCLOSURE OF PERSONAL INTERESTS IN COMMERCIAL ENTITIES:

Disclosure of any direct financial benefit derived from work performed for industry (per company), or any direct finan-

cial interest or investment in industry (per company) in the previous 3 years relevant to official activities of the ATS. Financial relationships of any amount are relevant. The following categories should be included:

A. Employment by a commercial entity (*Disclosure of salary amount for full time employees is not required.*);

B. Consultancy(ies);

C. Board or Advisory Board;

D. Lecture fees (honoraria);

E. Expert witness fees;

F. Industry-sponsored grants (received or pending) including contracted research;

G. Patents received or pending;

H. Royalties;

I. Stock ownership or options, including sector mutual funds with areas of concentration in an industry or industries relevant to the activity;

J. Other personal financial interests.

ii. DISCLOSURE OF NONCOMMERCIAL INTERESTS (relevant or potentially relevant to official activities of the ATS):

Disclosure of whether or not the individual has received support within the past three years from a *noncommercial (nonprofit) source* that has an interest in official activities of the ATS (e.g., a government, foundation, or other nonprofit source).

iii. DISCLOSURE OF INSTITUTIONAL FINANCIAL INTERESTS:

Disclosure (if the individual has knowledge) of whether his/her institution or employer has a financial relationship with a commercial entity that has an interest in official activities of the ATS (12). The individual is not required to make specific inquiries of the authorities of his/her institution.

iv. FINANCIAL RELATIONSHIPS SHOULD BE DISCLOSED WITHIN DOLLAR AMOUNT RANGES:

Dollar amount ranges are specified by the Committee on Ethics and Conflict of Interest. Dollar ranges will be considered by the chair of the official ATS activity (or other authorized parties involved in the disclosure review process) as a factor in weighing the significance of COI, and determining appropriate measures to take to resolve COI. Dollar amounts will not be published or reported within ATS conferences or projects or otherwise reported by ATS to the public, with the exception of ATS official documents, where the dollar amount range of each participant's relationship per company (for the 3 years prior to submission of the draft document to the ATS Board of Directors) should be included in the disclosure statement that is published with the document, in the manner determined by the Publications Policy Committee, the Journal Editors, and the Documents Editor.

NOTE: An individual employed by an industry relevant to the subject matter should disclose his/her employer, but is not required to disclose salary amount.

d. Disclosures and conflicts should be re-reviewed by participants in an ongoing manner. Any relevant new developments

that may influence or be perceived as influencing an individual's participation in an official ATS activity should be disclosed by the individual and brought to the attention of all decision makers within the activity (e.g., project/conference chairs, organizing or writing committee members, conference session faculty).

e. All participants (committee/panel members and/or presenters) should be asked and reminded to consider their own conflicts and conflicts of others during discussions and decision making. Participants should abstain from discussion and voting if they or a sizable proportion of the other participants identify a COI.

2. REVIEW OF POTENTIAL PARTICIPANTS' COI:

a. Those choosing participants for official ATS activities should review disclosures before deciding on participants, and exclude participants if there is a non-resolvable conflict of interest.

b. Chairs, organizers, and others with COI review responsibilities should receive step-by-step procedures that clearly and simply articulate what happens and who is responsible at each stage of disclosure and review, and that provide guidance in evaluating the relevance and significance of the COI and determining appropriate methods of resolution. (See SAMPLE GUIDELINES, APPENDIX 3.)

For the following categories of participation in ATS, the step-by-step procedures for COI review should include:

i. *Candidates for ATS office:*

The ATS Nominating Committee should receive and review COI disclosures from individuals under consideration as nominees for office and should give consideration to any identified COIs and whether they are resolvable through disclosure or recusal alone, or require additional consideration. The COI disclosures of candidates for Assembly Chair and other potential members of the ATS Board of Directors should also be reviewed by the Assembly's executive committee and by the ATS Nominating Committee before election or appointment.

ii. *Candidates for project/conference chair or organizer:*

Appropriate ATS Assembly oversight committees (i.e., planning committees and/or program committees), or appropriate non-Assembly Committees in situations where they have oversight (e.g., the Education Committee for educational activities or the Documents Development and Implementation Committee for official documents), should review the disclosures of those submitting proposals for official ATS activities as part of their vetting of the proposal. If the chairs or organizers of official ATS activities differ from the original proponents of the projects, their disclosures should be reviewed by the relevant Assembly oversight committee.

iii. *Project or conference participants:*

Project or conference chairs or organizers should review the disclosures of participants (e.g., members of project committees and presenters at workshops and conferences) and may exclude participants if they conclude that COI are not resolvable. Written confirmation of this review, including a brief report of any COI identified and the means by which the COI will be resolved, should be submitted to designated ATS staff and to the chair of the oversight Assembly or committee.

iv. *Individuals employed full-time by a company or industry relevant to the subject matter:*

Careful consideration must be given regarding participation of individuals employed full-time by a company or industry that is relevant to the subject matter of an official ATS activity. For example, as previously noted, physicians and scientists employed by the pharmaceutical and/or medical device industry make important and often unique contributions as ATS members and participants in ATS activities. At times, the commercial interests of their employer can by their nature cause or be perceived as causing a COI that might affect the individual's participation in ATS activities that are relevant to these interests. The relevance and significance of the conflict may require that the individual or organizer take steps beyond disclosure of the relationship, such as recusal or excusal from roles or decision-making in ATS activities seen as relevant to employer interests. In particular, roles within ATS that control or may be perceived as controlling ATS decision-making (e.g., chair of an Assembly responsible for the development of documents and projects on subject matters of commercial interest to an individual's employer, or a member of a writing committee of a document on such subject matters) should be avoided. ATS members and other individuals employed by industry may be consulted by project and conference organizers and committees in a manner consistent with standards to be set by the ATS Committee on Ethics and Conflict of Interest and the ATS Documents Editor. ATS members and other individuals employed by industry may chair or present at a conference or session(s) within a conference if the appropriate oversight committee resolves the conflict in a manner that ensures objectivity, scientific rigor, and balance, and if an accredited Continuing Medical Education (CME) activity, in accordance with the requirements of the Accreditation Council for Continuing Medical Education and the AMA.

v. *ATS staff:*

Disclosure of COI should be required of ATS staff and made available to the ATS Executive Director for determination of whether any identified conflicts of interest require an individual's recusal or excusal from certain ATS roles or decision making, or other consideration to ensure that staff acts in the best interests of the ATS.

vi. *Assurance by Chairs that the procedures for COI disclosure management have been followed and reasonable decisions made:*

Chairs of the Assemblies or Committees that oversee official ATS activities should assure ATS that all required procedural steps have been taken, and that decisions made during the review process have been in compliance with this policy and are reasonable. Assembly Chairs may delegate this review to the Assembly Program Committee Chair for conference matters or Assembly Planning Committee Chair for project matters, or to another an appropriate Assembly member who does not have COI relevant to the subject matter.

vii. *Involvement of the Committee on Ethics and Conflict of Interest (and the Documents Development and Implementation Committee when pertaining to official ATS documents):*

Involvement of the above-noted committees may be requested or required in situations in which either a project chair's own COI require review or resolution, or a project chair or the oversight Assembly or Committee's chair

requests consultation or requires help to review or resolve COI.

viii. **Official peer review of ATS documents:**

The disclosures of participants involved in the writing of official ATS documents should also be reviewed as part of the official peer review process for ATS documents that is overseen by the Documents Development and Implementation Committee. Procedural steps for COI disclosure and review in connection with the development of ATS documents/guidelines may differ from other cases such as ATS conferences. ATS should develop a standard format that can be modified to suit varying circumstances.

3. DISCLOSURE OF COI TO PROJECT PARTICIPANTS:

Once the members of a project committee have been assembled, COI of members should be identified and discussed before beginning deliberations. Individual participants (including project chairs and panelists) should label where COI bear on specific recommendations.

4. RECUSAL OR EXCUSAL FROM CERTAIN DECISIONS OR RECOMMENDATIONS WHEN APPROPRIATE:

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. (For Example, as earlier noted, ATS members and other individuals employed by industry may have or be perceived as having conflicts of interest that warrant recusal from policy decision making on subjects of commercial interest to their employer, but can be encouraged to contribute to scientific dialog and other ATS activities in many other ways.)

5. DISCLOSURE OF COI TO USERS OF DOCUMENTS AND ATTENDEES OF CONFERENCES:

COI in official ATS activities should be minimized and transparent. ATS policies for COI disclosure and resolution should be publicly available for all users of ATS documents and attendees of ATS conferences (e.g., through posting on the ATS website). COI should be published with all ATS-sanctioned documents and made available to participants in all ATS conferences, and reference should be made to the policies (herein described) and processes used to identify and resolve COI during the project or conference'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. COI should be disclosed to participants of ATS CME activities and other educational activities in accordance with the Requirements of the Accreditation Council for Continuing Medical Education and the AMA for accredited CME.

6. Procedures for Handling Disputes in COI Resolution:

The ATS Ethics and Conflict of Interest Committee should develop and oversee the procedures and instruments used to disclose, review, and resolve COI, and should advise and assist chairs and organizers where necessary. Project chairs should first contact the chair or designee of the ATS Assembly or ATS committee overseeing the project. The project chair or oversight Assembly or Committee chair should then request the assistance of the Ethics and Conflict of Interest Committee

if necessary. Appropriate ATS staff should be available to advise and assist chairs and organizers throughout the process.

In instances where determination of COI and actions taken to resolve COI in official ATS activities has been disputed, an *ad hoc* adjudication committee of members appointed by the ATS President should be convened to address the matter. Such an *ad hoc* adjudication committee could include the Chair of the Ethics and Conflict of Interest Committee (or designee), Chair of the Documents Development and Implementation Committee (or designee), ATS Past-President (or designee), and Past-Chair of the Council of Chapter Representatives, in consultation with ATS legal counsel. Such an *ad hoc* committee could also review COIs of individuals choosing project participants or panelists.

CONCLUSIONS

Individuals with expertise in specific areas of health care often have potential COI, sometimes as a result of their usual professional activity. However, such COI require management to reduce the possibility of their influence on healthcare policy and decisions and to maintain the public's trust in professional organizations. The new ATS Policy on Management of COI in Official ATS Documents, Projects, and Conferences promises greater transparency in the declaration of potential COI. Generally, this policy is in agreement with policies of other organizations, but it provides improved and more explicit guidance for those making decisions about the management of COI in specific situations. Examples of these situations are provided in the appendices. The policy institutes a requirement for oral disclosure of COIs to other project participants and recusal from particular recommendations when appropriate. In addition to full disclosure to ATS via required disclosure forms, project committee members orally report to the rest of the committee any conflict of interest relevant to the project subject(s), to allow full committee knowledge and consideration as it proceeds. Once the members of a project committee have been assembled, COIs of members should be illuminated and/or discussed before beginning deliberations. Individual participants (including project chairs and panelists) should label where COIs bear on specific recommendations. Chairs and panelists should ensure that committees are reminded of the specific COIs before discussion of individual conclusions or recommendations on which those COIs bear. If the COIs are excessive, participants should recuse themselves, or chairs should recuse the participants, from discussions or decision-making on particular recommendations. For instance, a clinical researcher has received a honorarium (\$10,000) from a for-profit sponsor company "X" (Co. X: Value category 3, weight 3) that is related to exploring the efficacy of a medication that will be discussed by a guideline panel making recommendations regarding this and other interventions (relevance 3). The total score based on a weight of 3 and relevance of 3 would be 9. Actions by those overseeing membership on committees may include the request for the panel member to refrain from participating in discussion about this particular product. Another mechanism for protecting against the influence of COIs on specific recommendations is to ensure that the recommendations in an official ATS document reflect the best available evidence. Where COI has been identified, peer review of content by an unconflicted project chair, the committee as a whole, and/or outside peer reviewers can attest that the content is evidence-based. Furthermore, this policy includes information about non-monetary COI, including potential academic conflicts. It has been in effect as of March

2008. Application and ongoing evaluation of the policy will inform the ATS about its usefulness in specific settings.

Conflict of Interest Statement: H.J.S. has no personal payments from pharmaceutical industry, but in the past 3 years honoraria were deposited into research accounts or received by a research group that he belongs to from Chiesi Foundation (honorarium), Lilly (honorarium), Pfizer (lecture fee, honorarium), and UnitedBioSource (honorarium) for development or consulting regarding quality-of-life instruments for chronic respiratory diseases and as lecture fees related to the methodology of evidence-based practice guideline development and/or research methodology. He is documents editor for the American Thoracic Society that receives funding from for-profit organizations for activities other than guideline or ATS statement development. Other institutions or organizations that he is affiliated with likely receive funding from for-profit sponsors that are supporting infrastructure and research that may serve his work. M.O. does not have a financial relationship with a commercial entity that has an interest in the subject of this manuscript. J.M. has patents and pending patents as part of his official activities as a Principal Investigator at the National Institutes of Health. As required for NIH employees, he assists in the commercialization of these inventions. C.M. does not have a financial relationship with a commercial entity that has an interest in the subject of this manuscript. G.W. does not have a financial relationship with a commercial entity that has an interest in the subject of this manuscript. L.S. has received grants from Altus Pharmaceuticals (< \$1,000), Vertex Pharmaceuticals (< \$5,000), Inspire Pharmaceuticals, Inc. (< \$1,000), Gilead Sciences (< \$1,000), and Pharmaxis Ltd (< \$1,000). J.O. has provided expert testimony for asbestos induced lung disease, including plaintiff work chart review (\$25,000 and patient evaluations \$105,000), was a member of Advisory Boards to GlaxoSmithKline, Boehringer Ingelheim, Pfizer, Sepracor, AstraZeneca, and Talecris and a speaker for GlaxoSmithKline, Pfizer, and Sepracor. S.M. has no personal payments from or financial interests in commercial entities or institutions relevant to the American Thoracic Society; employed by the American Thoracic Society, which receives funding from for-profit organizations. L.L. has no personal payments from or financial interests in commercial entities or institutions relevant to the American Thoracic Society; employed by the American Thoracic Society, which receives funding from for-profit organizations. R.J. received within the last 3 years honoraria and travel support from Boehringer Ingelheim (\$4,000) and GlaxoSmithKline (€3,000). He is a deputy editor of a medical journal funded partially by industry advertisement.

Acknowledgment: The authors thank Mrs. Judy Corn for staffing the documents committee and her contribution to reviewing the literature. They also thank ATS leadership and others reviewing drafts of this manuscript and policy.

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APPENDIX 1

Board-approved text of online American Thoracic Society Disclosure Form.

Subject to future revision by the ATS Ethics and Conflict of Interest Committee

AMERICAN THORACIC SOCIETY DISCLOSURE FORM

The purpose of disclosure is to identify an individual’s “competing interests”, so that the individual and ATS members responsible for oversight may learn whether there is or may be a conflict of interest that would affect the individual’s participation in official ATS activities.

PART 1: DISCLOSURE OF PERSONAL FINANCIAL INTERESTS IN COMMERCIAL ENTITIES:

For each of the areas of potential personal financial interest noted below, if at present or within the past three years you have had the stated relationship with a commercial entity (company) that has an interest in official ATS activities, or you know you will have or expect to have in the future such a personal financial interest, please do the following. (Note: tobacco-related commercial entities, as defined by ATS policy, should be included here also. However, additional questions about tobacco entities specifically will also be asked in Part 4 of this form.):

1. Click “Yes” or “No.”
2. Under “Commercial Entity,” when asked, type the name of any applicable company for that category; one company per line.
3. Under “Whose Relationship,” use the drop-down boxes to note if “own” or “spouse/life partner” or “dependent.”
4. Under “Dollar Range”, use the drop-down boxes to note the dollar range of the financial interest for the past three years combined, using one of the following ranges: “Up to \$ 1,000,” “\$1,001–5,000,” “\$5,001–\$10,000,” “\$10,001–\$50,000,” “\$50,001–\$100,000,” “\$100,001 or more.”

ATS policy requires dollar ranges solely for confidential consideration of authorized COI reviewers. Dollar ranges will not be made public in ATS activities (including ATS conferences and the ATS Website) and are not required to be included in Disclosure Slides shown at the International Conference. Exceptions: ATS Journals will continue to cite dollar ranges in the COI statements published with manuscripts, per previous practice. ATS documents (e.g., official statements) will also cite dollar ranges, consistent with Journals practices.

Type-in boxes below will expand as needed to fit the text you enter. If you have more than five entries to disclose for any one category, please enter them, and/or any other disclosures not covered by categories “A” through “I” below, in category “J. Other.”

Note: This sample does not include the click-to-respond buttons and type-in and drop-down boxes that appear in the actual form. Only text is shown below.

A. EMPLOYMENT BY A COMMERCIAL ENTITY

(Disclosure of salary amount for full time employees is not required.)

- Yes
- No

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse’s, etc.) and the dollar range:

Commercial Entity	Whose Relationship	Dollar Range	Description (Optional)
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B. CONSULTANCY(IES)

- Yes
- No

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse’s, etc.) and the dollar range:

Commercial Entity	Whose Relationship	Dollar Range	Description (Optional)
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C. BOARD OR ADVISORY BOARD

- Yes
- No

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse’s, etc.) and the dollar range:

Commercial Entity	Whose Relationship	Dollar Range	Description (Optional)
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D. LECTURE FEES PAID BY COMMERCIAL ENTITY (HONORARIA)

- Yes
- No

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse’s, etc.) and the dollar range. If the lecture occurred within a promotional activity of a pharmaceutical company rather than within a nonpromotional CME activity, please type “promotional” within the “Description (Optional)” column. (Note: ATS now asks for disclosure to ATS of promotional speaking engagements due to a December 2008 agreement between a pharmaceutical company and regulators to not fund CME involving presenters who have had a promotional speaking engagement on behalf of that company within past 12 months. ATS does not at this time require that this be included within published disclosure summaries or disclosure slides.)

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse’s, etc.) and the dollar range:

Commercial Entity	Whose Relationship	Dollar Range	Description (Optional)
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E. EXPERT WITNESS

- Yes
- No

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse's, etc.) and the dollar range:

Commercial Entity	Whose Relationship	Dollar Range	Description (Optional)
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F. INDUSTRY-SPONSORED GRANTS (RECEIVED OR PENDING) INCLUDING CONTRACTED RESEARCH

- Yes
- No

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse's, etc.) and the dollar range. For research, dollar range should reflect estimate of total dollars and products (equipment/reagents, etc.) you and your institution received, not only what you personally received. If you wish to identify grant as "collaborative" or "institutional" rather than "individual", type that in Description box.

Commercial Entity	Whose Relationship	Dollar Range	Description (Optional)
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G. PATENTS RECEIVED OR PENDING

- Yes
- No

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse's, etc.). Under "Description" type a brief description of the subject matter of the patent(s). Also type the dollar range if there was any financial benefit for you or your institution within the past three years.

Commercial Entity	Whose Relationship	Description (Required)
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H. ROYALTIES FROM A COMMERCIAL ENTITY

- Yes
- No

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse's, etc.) and the dollar range:

Commercial Entity	Whose Relationship	Dollar Range	Description (Optional)
-------------------	--------------------	--------------	------------------------

I. STOCK OWNERSHIP OR OPTIONS, including sector mutual funds with areas of concentration in an industry or industries relevant to the activity

- Yes
- No

Type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse's, etc.) and the dollar range:

Commercial Entity	Whose Relationship	Dollar Range	Description (Optional)
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J. OTHER PERSONAL FINANCIAL INTERESTS

(including if you had more than five entries to disclose for any one of the previous categories)

- Yes
- No

If yes, type the name(s) of each commercial entity in this category (one company per line), and use the drop-down boxes to note whose relationship (yours or spouse's, etc.) and the dollar range. Also, under "Description", type a brief description; note the category of the financial interest if it fits "A" through "I" above.

Commercial Entity	Whose Relationship	Dollar Range	Description (Required)
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PART 2: DISCLOSURE OF PERSONAL FINANCIAL INTERESTS IN NONCOMMERCIAL ENTITIES (i.e., that are relevant or potentially relevant to official activities of the ATS)

If at present you are receiving, or within the past three years you have received support from a noncommercial funding source that has an interest in official ATS activities (e.g., a government source such as the NIH, or a foundation, or other nonprofit source), OR you know you will have or expect to have in the future such a relationship, please:

1. Click “Yes” or “No.”
 2. Under “Entity Name,” type the name of the noncommercial (nonprofit) entity(ies) (one per line).
 3. For each noncommercial (nonprofit) entity you cite, use the drop-down boxes to note:
 - a. the type of relationship;
 - b. if the relationship is yours or that of your spouse or life partner or dependent;
 - c. the dollar range for the past three years combined.
- Yes
 - No

If yes, type the name(s) of each noncommercial (nonprofit) entity, and use the check-off boxes that will appear to provide the information noted above:

Entity Name	Type Of Relationship	Whose Relationship	Dollar Range	Description (Optional)
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PART 3: INSTITUTIONAL FINANCIAL INTERESTS:

Do you have knowledge of your institution or employer (or that of your spouse or life partner or dependent) having a significant financial relationship with a commercial entity that has an interest in official activities of the ATS? For example: a commercial entity that you know has provided significant support to your institution or employer, or has a significant contractual relationship. Please note: in regard to this question, as with ATS Journal policy on disclosure of relevant institutional financial interests, ATS does not require individuals to make specific inquiries of the authorities of their institution.

1. Click “Yes” or “No.”
 2. For each significant financial relationship of your institution that is already known to you:
 - a. type the name of the commercial entity(ies) involved;
 - b. type a brief description of the institution or employer’s relationship with that commercial entity;
 - c. use the drop-down boxes to disclose the type of relationship, if the institution with relationship is yours or that of your spouse or life partner or dependent, and the dollar range if known. Also under “Description” type in additional information if useful.
- Yes
 - No

If yes, type the name(s) of each entity, and use the drop-down or write-in boxes to provide the information noted above:

Entity Name	Type Of Relationship	Whose Relationship	Dollar Range	Description (Optional)
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PART 4: TOBACCO ENTITIES:

Since they involve a commercial entity that has an interest in official ATS activities, any personal financial interests that you (or your spouse or life partner) have had with commercial entities (companies) involved in tobacco (as defined within the ATS policy; see definition below) during the past three years should have been disclosed within Part 1 of this form. However, in addition, the ATS Policy Governing Relationships Between the Tobacco Industry, ATS Members, and Nonmembers Who Participate in ATS Activities:

(A) requires “disclosure of present or past relationships with a tobacco entity (as defined within the policy) **within the past ten years**, including present and past ownership of stocks or options of a tobacco entity (other than mutual funds), and those of the individual’s spouse or life partner.”

(B) requires specific distinction of any relationships **within the past twelve months or at present**

Please also note:

- ATS policy defines tobacco entities as including: (1) all companies engaged in the manufacture of tobacco products; (2) all affiliates and subsidiaries of such companies for which it may be reasonably concluded, as a result of publicly available information, that the affiliate or subsidiary’s ownership, activities, and/or image benefits the sale of tobacco products; (3) all advocacy groups that receive tobacco industry support to promote the use of tobacco products and/or impede policies to prevent tobacco-caused disease.
- A spouse or life partner’s relationship with the tobacco industry or tobacco stock/option ownership must be disclosed below, but will not be considered to be a relationship of the ATS member or other ATS participant with the tobacco industry, nor will it be considered as grounds for any automatic limitations on the ATS member or other participant’s participation in the ATS activities specified in the policy noted-above.

Therefore, please do the following:

1. Click “Yes” or “No.”
2. Under “Entity Name,” type the name of the tobacco entity(ies).
3. Use the drop-down boxes to note: (a) the type of relationship (comparable to categories A through J in Part 1 of this form), and (b) whether the relationship is yours or that of spouse or life partner (c) the dollar range for each for the past three years (or most recent three years) combined.
4. Under “Dates/Description,” please type the calendar years in which the relationship existed (e.g., 2005-6) and any other description that would be helpful in COI review.

A. Any relationships with tobacco entities within the past ten years?

- Yes
- No

Please provide details requested below even if you previously entered information about a tobacco entity within Part 1 of this form:

Entity Name	Type Of Relationship	Whose Relationship	Dollar Range	Dates/Description (Required)
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B. If yes: any relationships with tobacco entities within the past twelve months or at present, specifically?

- Yes
- No

Although you provided this information within your previous answer, for any relationship with a tobacco entity that occurred within the past twelve months or exists at present, please below:

- 1) reenter the Entity Name and use the drop-down menus to re-answer the other columns, including for Dollar Range the total value of any grant or products related to this received within most recent 3 years;
- 2) if the relationship ended within the past 12 months (and hasn’t been renewed), please type in the Dates/Description column the word “ended” and type the month and year in which it ended (e.g., December 2008). If the relationship is scheduled to end soon, type in “ending [month /year]”. ATS will use this information in determining eligibility for ATS activities for which ATS policy requires that there be no tobacco industry affiliation. ATS will otherwise assume the relationship is current and ongoing.

Entity Name	Type Of Relationship	Whose Relationship	Dollar Range	Dates/Description (Required)
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PART 5: OTHER:

If there is anything else that you think could affect your objectivity or independence or the perception by others of your objectivity or independence in relation to your ATS activities, please click the YES button below and briefly describe below. If you have nothing else to declare, please click the NO button.

- Yes
- No

Description:

PART 6: ATTESTATION:

I attest that the information on this form is correct. Further, I acknowledge that keying in my name and corresponding date at the top of this form indicates my assent to this agreement and is equivalent to my signature.

APPENDIX 2

AMERICAN THORACIC SOCIETY
OPTIONAL METHOD FOR EVALUATING THE SIGNIFICANCE
OF A POTENTIAL COI: SIGNIFICANCE SCALE

User instructions

Step 1. In Table A1, select a monetary and/or nonmonetary “value” on the scale labeled adding up all declared values for the 3 years prior to submission of the project or application per company or commercial sponsor (*see* examples in the legend to the table).

Step 2. Determine the “weight” using the column labeled “weight.”

TABLE A1. “WEIGHT” OF POTENTIAL CONFLICT OF INTEREST (COI) BASED ON “VALUE”

Value Category (Monetary and/or Nonmonetary)*	Weight [†]
1. Up to \$1,000 [‡]	1
2. \$1,001–5,000 [§]	2
3. \$5,001–10,000 [¶]	3
\$10,001–50,000	
\$50,001–100,000	
\$100,001 or more	

* Select a value category for the potential COI that reflects both monetary and non-monetary value combined (*see* [‡], [§], [¶] below to determine any non-monetary value). Include direct or indirect financial interests such as research grants or similar (based on categories and ranges specified by the ATS Committee on Ethics and Conflict of Interest) in US\$; amounts will not be published or reported within ATS conferences or projects or otherwise reported by ATS to the public, with the exception of ATS official documents, where the dollar amount range of each participant’s relationship per company or commercial sponsor (for the 3 years prior to submission of the draft document to the ATS Board of Directors) should be included in the disclosure statement that is published with the document. This information will be available ONLY to chairs and organizers of official ATS activities who will evaluate the COI disclosures and to the ATS Board of Directors and the Committee on Ethics and Conflict of Interest, if necessary.

[†] Used with relevance rate (*see* Table A2) to calculate significance.

[‡] Example of nonmonetary value in category 1: a pen, pencil, cell phone.

[§] Example of nonmonetary value in category 2: paid tickets to the Super Bowl or World Cup final for the family.

[¶] Example of nonmonetary value in category 3: free first class ticket to Australia from North America for spouse or family.

Step 3. Rate the “Relevance” of a potential conflict of interest (Table E2) by choosing descriptor or number:

Step 4. Calculation:

Total score = weight (Table A1) × relevance (Table A2)

Score range: 0 to 18

Use this significance score to determine the action required to manage or resolve COI (*see* Step 5).

Step 5. Interpretation and action as described in accompanying ATS resources:

Total score: 0 to 2—no further action required.

Total score: 3 to 18—evaluate whether further action is required, including in regard to membership on a workshop panel or refraining from specific activities such as discussing or voting on specific recommendations.

For ATS “COI resolution options”, *see* Section V, Part 2 of the ATS “Policy on Management of COI . . .”, “*Review of Potential Participants’ COP*”; Appendix 3, “*Sample COI Resolution Guidelines*”; or other COI resolution guidelines issued by ATS subsequently.

Examples of interpretation:

A statistician has received \$30,000 in consulting fees and \$25,000 as research grant from a spirometer device company “Y” (Company Y: Value category 3, weight 3) two years ago. He is invited to work on a meta-analysis on implementing pneumonia guidelines by an ATS writing group. The panel chair judges that the involvement with company “Y” has no relevance to the Pneumonia guidelines (relevance: 0). The total score = weight 3 × relevance 0 = 0. No further action is required.

A clinical researcher has received a honoraria (\$10,000) from a for-profit sponsor company “X” (Company X: Value category 3, weight 3) that is related to exploring the efficacy of a medication that will be discussed as one of many medications by a guideline panel making recommendations this and other interventions (relevance 3). The total score = weight 3 × relevance 3 = 9. Actions by those overseeing membership on committees may include the request for the panel member to refrain from participating in discussion about this particular product.

TABLE A2. RELEVANCE TO THE TOPIC

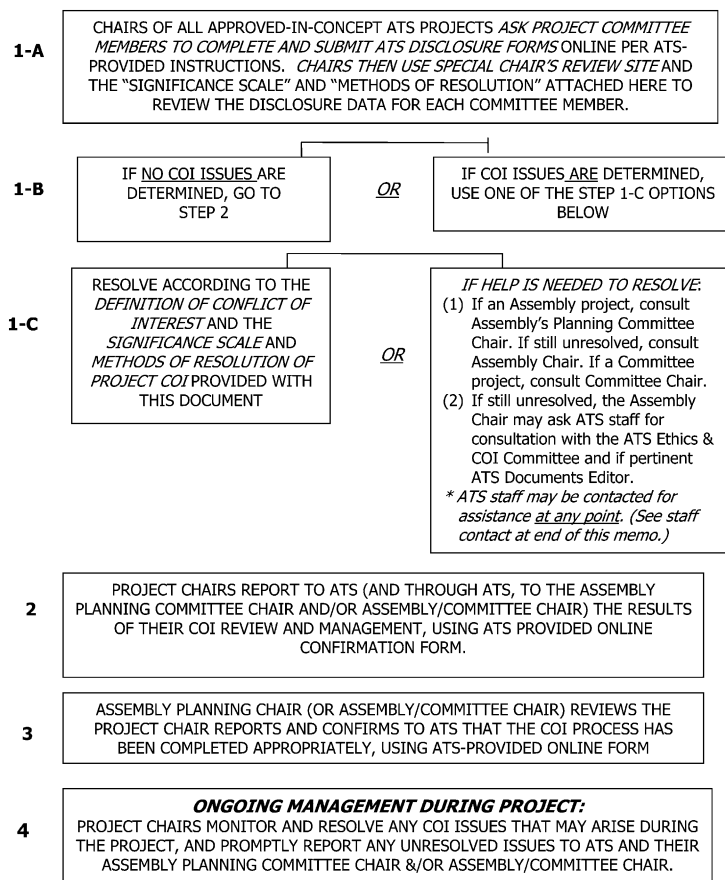
	None	Very Low	Low	Moderate	Moderate to High	High	Very High
Relevance	0	1	2	3	4	5	6
Description	Topic of interest is not relevant and unrelated to a competing interest			Topic of interest is somewhat relevant and related to a competing interest		Topic of interest is highly relevant or directly related to the declared competing interest	
Examples	A statistician involved in conducting meta-analysis on implementing pneumonia guidelines who consulted for a spirometer device company	A methodologist has given a methods focused presentation at an event sponsored by a for-profit organization whose products will be discussed by a guideline panel	A researcher has received personal honoraria for speaking about medications that is produced by a sponsor. Other products of this sponsor will be discussed by a guideline panel	A researcher has received personal honoraria for speaking about a medication that will be the topic of a recommendation in a guideline	A researcher's career is focused on the exploration of a topics about which a recommendation for additional resources will be made to a funding agency	A clinical researcher has received a research grant and/or honoraria from a for-profit sponsor that is related to exploring the efficacy of a medication that will be discussed by a guideline panel. The guideline panel may make recommendations for its use.	A researcher is the owner or major shareholder of a company that produces a device or medication about which a recommendation will be formulated by a guideline panel

APPENDIX 3

PROCEDURE FOR RESOLVING CONFLICT OF INTEREST (COI) IN 2009 ASSEMBLY/COMMITTEE PROJECTS

These procedures are based on the ATS POLICY ON MANAGEMENT OF CONFLICT OF INTEREST IN OFFICIAL ATS DOCUMENTS, PROJECTS, AND CONFERENCES and the ATS POLICY GOVERNING RELATIONSHIPS BETWEEN THE TOBACCO INDUSTRY, ATS MEMBERS, AND NON-MEMBERS WHO PARTICIPATE IN ATS ACTIVITIES, as approved by the ATS Board.

I. Flow Chart of the Process:



II. Assessing Identified Conflicts of Interest:

Project Chairs (and oversight Assembly Planning Committee Chairs and/or and Assembly or Committee Chairs) are encouraged to use (a) the following *definition of conflict of interest* and (b) the *significance scale* accompanying this memo as a guide in determining significance and the level of resolution needed.

A) DEFINITION OF CONFLICT OF INTEREST (COI)*:

* Definitions below are from the ATS Policy on Management of COI and the ATS Tobacco Relationships Policy. Full policies are available at the COI Management section of the ATS website: <http://www.thoracic.org/sections/about-ats/coi-management/index.html>.

A divergence between an individual's private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual's professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams or community standing.

A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind. Examples:

- i. All financial relationships, including ... employment by a commercial entity; consultancy(ies); Board or Advisory Board [membership]; lecture fees (honoraria); [serving as an] expert witness; industry-sponsored grants (received or pending) including contracted research; patents received or pending; royalties; stock ownership or options, including sector mutual funds with areas of concentration in an industry or industries relevant to the activity; other personal financial interests. . . ;
- ii. Personal, intellectual or academic relationships that interfere with an individual's ability to consider or interpret the full breadth of available data or alternative points of view objectively. Examples include inability to review a grant, manuscript, or proposal objectively due to competition for funding, timing of publication, or professional stature.

In addition, specific to relationships with the tobacco industry, ATS policy now regards individuals who have a current relationship (or within past 12 months) with a tobacco entity to be ineligible for certain ATS roles, including the following relevant to ATS Assembly/Committee projects: "serve as a planner (organizer) or chair of ATS scientific and educational programs," "serve on the writing committee of an ATS statement or guideline." If the relationship is limited to personal holdings, divestiture is permitted. (Go to the COI Management section of the ATS website to see the full Tobacco Relationships Policy for more information: <http://www.thoracic.org/sections/about-ats/coi-management/index.html>.)

B. SIGNIFICANCE SCALE

(See Significance Scale that accompanies this Procedures document.)

III. Methods of Resolution:

The following are regarded by ATS as appropriate methods of resolving COI affecting 2009 ATS Assembly/Committee projects. Circumstances may warrant more than one of the following:

1. BALANCE OF OPINION

Projects should be designed to reflect a balance of opinion. However, structuring the format of an activity to be "balanced" does not alone resolve an identified conflict of interest. Other methods of resolution as recommended here should also be used.

2. ORAL DISCLOSURE OF COI TO PROJECT PARTICIPANTS; RECUSAL FROM PARTICULAR RECOMMENDATIONS WHEN APPROPRIATE

In addition to full disclosure to ATS via required disclosure forms, project committee members orally report to the rest of the committee any conflict of interest relevant to the project subject(s), to allow full committee knowledge and consideration as it proceeds. Once the members of a project committee have been assembled, COI of members should be illuminated and/or discussed before beginning deliberations. Individual participants (including project chairs and panellists) should label where COI bear on specific recommendations. 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 excessive, participants should recuse themselves, or chairs should recuse the participants, from discussions or decision-making on particular recommendations.

3. PEER REVIEW TO ENSURE RECOMMENDATIONS REFLECT THE BEST AVAILABLE EVIDENCE

Recommendations should always reflect the best available evidence. All research reported should conform to generally accepted standards. Where COI has been identified, peer review of content by the project chair, committee as a whole, and/or outside peer reviewers can attest that the content is evidence-based.

4. DISCLOSURE TO CONSUMERS OF ATS DOCUMENTS AND ATTENDEES OF ATS CONFERENCES

The perception of COI in ATS activities should be minimized. Though it is likely impossible to have ATS activities without any potential COI, the process for declaring and resolving COI can be made transparent. COI should be published with all ATS-sanctioned documents, and reference should be made to the policies and processes used to identify and resolve COI.

5. THE INDIVIDUAL DOESN'T PARTICIPATE IN THE PROJECT

At times, the ATS (i.e., chairs of ATS projects, Assembly/Committee Chairs or their designees, and/or other authorized ATS officials) may judge that an individual's conflict of interest cannot be adequately resolved through the above methods, and it would be in the best interests of the ATS for the individual not to participate in the project. For example:

1. Individuals employed by an industry relevant to the subject matter should generally be regarded as inappropriate for roles that may control decision-making affecting ATS policies in that subject area - such as chair of an Assembly responsible for development of documents and projects on that subject matter, or a member of a writing committee of a document on that subject matter. Individuals employed by industry relevant to the subject matter may be consulted by writing committees in a manner acceptable to standards to be set by the ATS Documents Editor. Individuals employed by industry may chair or present at a conference or session(s) within a conference if the appropriate oversight committee manages the COI in a manner that ensures objectivity, scientific rigor, and balance.
2. Individuals whose financial livelihood is principally as an independent contractor providing consultation/recommendations on a specific medical procedure may be inappropriate to chair an ATS statement development project on that topic, due to the potential that it would be perceived that he/she has direct financial benefit from ATS recommendations on that topic.

IV. ATS Resources:

For staff assistance or to contact the Ethics & COI Committee or ATS Documents Editor about project COI management, contact Shane McDermott, Senior Director, Ethics & COI Policies at smcdermott@thoracic.org or (212) 315-8650. In his absence, contact Barbara Horner, Manager, at bhorner@thoracic.org or (212) 315-8639:

For general information including ATS COI policies, see the COI Management section of the ATS website: <http://www.thoracic.org/sections/about-ats/coi-management/index.html>.

APPENDIX 4

COI Policies - Summary of Selected Other Societies

The table below has been compiled by staff to the ATS Documents Development & Implementation Committee. Data reflects analysis of organizational policies available online, including those of the American College of Physicians (ACP), American College of Chest Physicians (ACCP), American Medical Association (AMA), Society for Critical Care Medicine (SCCM), International Committee of Medical Journal Editors (ICBMJE), and the World Health Organization (WHO). Each organization's policy was evaluated on the following: Definition of COI; Timing of Disclosure; Level of Disclosure; Disclosure Period; COI Review Elements; Management Strategies.

Key: X = item is included in policy. Additional information about specific policies has been provided in the Notes section.

7. NOTES/COMMENTS:

Most of the societies provide an illustrative list of possible financial conflicts of interest rather than an exhaustive one. If one of the above listed examples was not mentioned in a policy and/or the example was not relevant, a "N/A" was placed in that category; however, if the policy explicitly stated that there was not a specific conflict of interest, "No" was placed in that category. Also, if a policy did not contain enough information pertaining to a specific question, "N/A" was placed in the category.

The SCCM states, "Financial interest or other relationship can include such things as... [being a] major stockholder." However, a percentage of stock ownership constituting "major" is not reported.

The AMA states, "Only those investments that constitute a significant financial investment raise a concern about a possible conflict of interest," and that "'ownership of a material financial interest' shall mean holding a financial ownership interest of 5% or more, or holding a financial ownership interest which contributes materially to the Trustee's, Member's or Senior Manager's income, or holding a position as proprietor, director, managing partner or key employee."

The AMA considers the retention of an honorarium for an AMA related engagement to be a conflict of interest and requires that all honoraria received by the individual for AMA-related engagements shall be given to the association. The AMA also requires council and committee members to complete a COI form annually.

In terms of the level of disclosure, the AMA requires disclosure of "material financial interests" which is defined to mean "holding a financial ownership interest of 5% or more, or holding a financial ownership interest which contributes materially to the Trustee's, Member's or Senior Manager's income, or holding a position of proprietor, director, managing partner or key employee."

The AMA COI Review Bodies are its Board Committee on Organizations and Operations, and the full Board of Trustees.

In terms of management strategies, AMA Senior Managers shall not be involved in making the final decision on any issues relating to the provision of the goods and services by any company in which the Senior Manager or any extended family member owns a material financial interest. Also, a Senior Manager shall not be involved in the preparation of any arrangement to acquire such goods and services. Finally, limitations shall be placed on a Senior Manager's activities in those cases where the Senior Manager cannot separate his or her personal interests from the interest of the AMA and render a fair and independent decision.

The ICMJE requires authors to describe the role of any study sponsors, if they should exist. Also, ICBMJE states, "Editors should avoid selecting external peer reviewers with obvious potential conflict of interests, for example, those who work in the same department of institution as any of the authors."

The information from *The Endocrine Society* was reviewed, but it was not evaluated using this tool. The guidelines presented offer suggestions as to what should be done in the event of a possible conflict of interest rather than listing rules that are to be strictly enforced by a formal policy. A variety of possible COIs in areas including publications, relations with industry, clinical research, basic research, clinical practice, and the training of physicians and scientists are listed, and possible recommendations as how to rectify the situations are given.

Staff from the ACCP, SCCM, AMA, WHO, and ICMJE reviewed and confirmed this chart for accuracy prior to publication. The ACP's COI policy was being revised during the review period for this appendix and as such, ACP staff were not able to provide feedback.

	ACP	ACCP	AMA	SCCM	ICMJE	WHO
1. DEFINITION OF COI includes:						
<i>FINANCIAL:</i>						
Employment	X	X	X	X	X	X
Consultancies	X	X	X	X	X	X
Stock	X	X	X (if significant)	X (major stockholder)	X	X
Mutual fund holdings	No	No	X (if significant)	X	X	No
Honoraria	X	X	X-given to AMA	X	X	X
Paid expert testimony	X	X	N/A	X	X	X
Family members	X	X	X	X	N/A	X (partner)
Research grants	X	X	N/A	X	X	X
Patents	X	N/A	N/A	X	X	X
Royalties	X	X	N/A	X	X	X
Loans	N/A	X	X	X	X	X
Gifts	N/A	X	X	X	X	X
<i>INTELLECTUAL:</i> pre-existent beliefs	N/A	X	N/A	N/A	X	X
2. TIMING OF DISCLOSURE:						
Not specified						
Upon completion of project proposal		X				
Upon appointment of committee	X	X		X—at the invitation process for speakers		
Start of every committee meeting		X				X
Completion of draft manuscript					X	
Completion of final pre-pub manuscript		X				
Other		X (semi-annually)	X (annually)	X—for CMTE members		
3. LEVEL OF DISCLOSURE						
No amount specified	X		X(material financial interests)		X	X Except as noted below, no limits specified
Any amount		X		X		
>1000						X—nonmonetary
>3000						
>5000						
>10000						X—for investment interests
Other_____						
Direct payment		X				
Payment to research accounts		X				
Payment to institution		X			X	
4. DISCLOSURE PERIOD						
Not specified						
<12 months			X		X	
1 year	X	X		X		
3 years		X				X
5 years						
Other						
5. COI REVIEW ELEMENTS						
Not specified						
Panel chairs	X	X	N/A	X	X	X
Reviewer is primarily Secretariat and may include Panel Chairs						
Panel members	X	X	N/A			
Reviewers	N/A	X	N/A			
Is there a dedicated COI review body?	N/A	X	X			
6. MANAGEMENT STRATEGIES						
Not specified						
Explicit exclusion criteria?	X	X	N/A	N/A		X
Criteria customized to project role?	X	X	N/A	N/A		
Recusal from discussion	X	X	X	X		X
Possibilities are: total exclusion, partial exclusion and public disclosure, only public disclosure.						
Recusal from voting	X	X	X	X		X

APPENDIX 5

ACCME Standards for Continuing Medical Education

Emphases

As an accredited CME provider, the ATS must adhere to standards of the Accreditation Council for Continuing Medical Education (ACCME) for disclosure and resolution of COI in continuing medical education. The subjects of these standards are the ATS as CME provider and ATS educational activity. Noted below are pertinent minimum requirements for compliance with ACCME at the time of ATS Board approval of this policy, paraphrased here by using ATS relevant phrases:

- ATS must be able to show that every person in a position to control the content of a document has disclosed all relevant financial relationships with any commercial interest to the author. The ATS “relevant relationships” are financial relationships in any amount occurring within the past 12 months that creates a conflict of interest.
- An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, an author, and cannot have control of, or responsibility for the development, management, presentation, or evaluation of the document.
- The ATS must have implemented a mechanism to identify and resolve all conflicts of interest prior to the document being delivered to readers. When an individual discloses to readers any relevant financial relationship(s), the information must include:
 - a. The name of the individual
 - b. The name of the commercial interest(s)
 - c. The nature of the relationship the person has with each commercial interest
- The source of all support from commercial interest must be disclosed to readers
- When commercial support is “in-kind,” the nature of the support must also be disclosed to the learner.