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Version 10, effective January 1, 2022

## AMERICAN THORACIC SOCIETY

## MANAGEMENT OF CONFLICTS OF INTEREST: GENERAL POLICIES<sup>1</sup>

## I. INTRODUCTION:

The purpose of ATS policies on conflicts of interest (COI) is to establish a fair and transparent framework for individuals with conflicts of interest to remain as valued members or partners of the Society (ATS). The original policy was drafted by an ad hoc committee of the ATS Ethics and Conflict of Interest Committee, the ATS Documents Development and Implementation Committee, and ATS staff, after review, analysis and discussion of existing COI documents, policies, and procedures of the ATS and other professional organizations.

## II. GOALS:

To enhance the objectivity, scientific rigor, and transparency of official ATS activities by providing an explicit methodology for individuals who prepare an official ATS document (statement) or participate in an ATS project, conference, or other official activity, to:

- A. identify and disclose all personal or institutional "competing interests" that could cause or be thought to cause a "conflict of interest" (COI) affecting the individual's participation in the activity, and (b) mitigate (resolve) these conflicts.
- B. provide for disclosure and mitigation 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.
- C. comply with COI management requirements of relevant accreditors or standard-setting organizations, such as the Accreditation Council for Continuing Medical Education (ACCME), Council of Medical Specialty Societies (CMSS), and International Committee of Medical Journal Editors (ICMJE). For example, this includes complying with the ACCME *Standards for Integrity and Independence in Accredited Continuing Education*, which require that all CME of accredited providers of continuing education such as the ATS be free of commercial bias and marketing, and with regard to competing interests, requires disclosure, review, and mitigation of relevant financial relationships of planners and presenters of continuing medical education (CME) with "ineligible companies" (the types of organizations that may not be accredited in the ACCME system).<sup>2</sup>
- (1) The name of this policy when originally enacted was *Policy on Management of Conflict of Interest in Official ATS Documents, Projects, and Conferences.* It has since been renamed as *ATS Management of Conflicts of Interest: General Policies* due to subsequent ATS policies and procedures that address specific aspects of ATS operations, e.g., clinical practice guidelines, ATS Journals, involvement with the tobacco industry and/or cannabis industry, patient/family education, and ethical conduct and professionalism in ATS activities. Links to these subsequent policies are provided on page 12 of this policy.
- (2) A link to the ACCME *Standards for Integrity and Independence in Accredited Continuing Education* is available on page 12 of this policy, or it may be obtained at <a href="https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce">https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce</a>.

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Version 10, effective January 1, 2022

Page 2 (of 12)

## III. UNDERLYING PRINCIPLES:

- A. The American Thoracic Society (ATS) has confidence in the integrity of its members and others who participate in official ATS activities.
- B. The ATS membership is diverse. 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 its members, and affirms the value of different experiences and points of view. Because of the diversity of our members' affiliations their interests may at times compete with the interests of the ATS and represent a conflict of interest when participating in ATS activities.
- C. Many individuals have "competing interests" that may cause conflicts of interest. A conflict of interest depends on the situation, and not on the character of the individual.
- D. Physicians, nurses, scientists, and other professionals employed by or affiliated with the pharmaceutical or medical device industries or other industries relevant to ATS interests, and who serve as ATS members or otherwise contribute to ATS activities, make important and often unique contributions to the ATS mission. Some members receive industry funding to consult, lecture, participate in industry scientific advisory boards, conduct research, or provide other services. 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, or may be thought to produce, conflicts of interest (COI) that can affect a person's participation in ATS activities, and so disclosure of such involvement must be transparent, and its management be guided by the highest ethical standards and codes of conduct.
- E. Conscious or subconscious influence because of conflicts of interest, 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. 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.
- F. Simple *a priori* declaration of COI is insufficient.
- G. ATS-designated reviewers of COI for official ATS activities must evaluate the COI disclosures of potential participants and take steps specified by the ATS to ensure that all relevant conflicts of interest are mitigated (including for CME, all relevant financial

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Version 10, effective January 1, 2022

#### Page 3 (of 12)

relationships). If necessary, the designated reviewer may require more information from the participant to assess and mitigate an identified COI. The ATS Ethics and Conflict of Interest Committee, designated ATS staff, and the ATS Executive Committee should at their discretion have opportunities to review the evaluation and resolution, if required, before final assignments to official ATS activities are made.

- H. Project committee members and/or conference or workshop participants shall 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.
- I. COI should be acknowledged in the final published document or other products of the project or conference, preferably with footnotes that allow users of the document or other products to access the policies that managed COI during the project or conference's development.
- J. The Editors of ATS Journals should ensure that COI disclosures are obtained from manuscript authors, reviewed as part of final editorial review, and made available to journal readers.

#### **IV. DEFINITIONS:**

## A. "Conflicts of interest" (COI) include:

- 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 is motivated by personal gain, such as financial, academic advancement, clinical revenue streams or community standing.
- 2. A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind. Examples:
- 3. 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.
- 4. 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.

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Version 10, effective January 1, 2022

#### Page 4 (of 12)

- 5. As defined by the ACCME, i.e., all relevant financial relationships held by CME planners and presenters with "ineligible companies" (types of organizations that may not be accredited in the ACCME system).<sup>2</sup>
- B. "Participants in official ATS activities" include but are not limited to those serving Society interests or recognized by the Society in an official capacity, such as: members of the ATS Board of Directors; ATS standing and ad hoc committees and task forces; Assembly leaders; the members of writing committees and/or organizing committees for official ATS documents and projects such as clinical practice guidelines and ATS patient/family education; planners and presenters in accredited CME activities at ATS conferences and other ATS-associated CME, such as chapter CME; the editors, authors and reviewers of manuscripts published in official ATS journals; nominees for ATS recognition awards; key ATS staff.
- C. "Relevant financial relationships with ineligible companies" are financial relationships with categories of industry that the ACCME considers ineligible for accreditation in the ACCME system. <sup>2</sup> ATS continuing medical education (CME) activities must comply fully with ACCME requirements of accredited providers of CME.

## V. PROCEDURES:

The following processes should be used to identify and manage COI for all persons holding roles in official ATS activities.

#### i. Self-Declaration to ATS:

- a) All participants in official ATS activities must disclose to ATS in writing, using ATS prescribed methods, all competing interests that could cause or be thought to cause a conflict of interest in relation to the subject matter of the activity. For CME, these must include all relevant financial relationships with ineligible companies, as defined by the ACCME.<sup>2</sup> Disclosures should be made <u>prior</u> 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 final approval of the role and commencement of the activity. The person must declare: all current and past interests relevant to the subject and scope of the matter for the period of two years prior to the date of declaration; any conflicts of interest relevant to the subject and scope of the matter that are expected to occur soon; knowledge of and compliance with ATS standards for ethical conduct and professionalism in ATS activities. Exception for interests involving the tobacco industry, vaping industry, and cannabis companies manufacturing and marketing inhaled cannabis products: all interests have existed within the discloser's professional career must be disclosed.<sup>1</sup>
- b) The means and requirements of disclosure for ATS Journals may differ, if necessary, e.g., to be consistent with the standards and procedures of relevant standard-setting

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Version 10, effective January 1, 2022

#### Page 5 (of 12)

organizations recognized by the ATS such as the International Committee of Medical Journal Editors (ICMJE) and Committee on Publication Ethics (COPE).

- c) All reviewers of ATS Journal manuscripts and ATS research program grants shall disclose relevant competing interests using ATS-prescribed methods.
- d) Disclosure procedures throughout the Society should be uniform and use a standardized online ATS questionnaire developed by staff and overseen by the ATS Ethics and Conflict of Interest Committee. The means and requirements of manuscript-specific disclosure for ATS Journals may differ if necessary to be consistent with standards and procedures of the International Committee of Medical Journal Editors (ICMJE).
- e) The standard ATS disclosure questionnaire should require:
  - Disclosure of personal interests in commercial enterprises, including all of the following that have existed within the past two years, or are expected to occur during the period in which the person will hold the official ATS role for which disclosure is required, and is broadly relevant to the scope of the official ATS activity for which the person is disclosing: all direct financial benefits or potential benefits derived from work performed for industry, reported per company; all personal financial interests or investment in industry, per company; all intellectual property rights and proceeds received or expected. For ATS CME, this must include all relevant financial relationships with ineligible companies as defined by the ACCME.<sup>2</sup>. Exception for personal interests involving the tobacco industry, vaping industry, and cannabis industry manufacturing and marketing inhaled cannabis products: all interests that have existed within the discloser's professional career must be disclosed.<sup>1</sup> Financial relationships of any amount are relevant. Examples of relationships to be disclosed include:
    - Ownership of or employment by a commercial entity (disclosure of salary amount for full time employees is not required.).
    - o Consultancies.
    - o Board member or Advisory Board or Committee member.
    - o Lecture fees and honoraria.
    - o Expert witness.
    - o Industry-sponsored grants (received or pending), including contracted research.
    - o Intellectual property rights including patents received or pending.
    - o Royalties.
    - Stock ownership or options, including sector mutual funds with areas of concentration in an industry or industries relevant to the activity.
    - Other transfers of value including in-kind gifts or benefits such as travel, accommodation, and meals.
  - <u>Disclosure of relevant non-commercial interests</u> (relevant or potentially relevant to the scope of the ATS mission), including disclosure of whether or not the person has

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Version 10, effective January 1, 2022

#### Page 6 (of 12)

received support within the past two years from a *non-commercial (non-profit)* source (e.g., government agency, foundation, or other nonprofit source) that has an interest in the scope of the ATS.

- The proceeds from or value of each interest shown in dollar amount ranges. Proceeds or value must be disclosed using specified dollar amount ranges. Dollar amount ranges shall be considered by the ATS-designated reviewers of disclosures as one factor in weighing the significance of a conflict of interest, to determine the appropriate measures to take to mitigate the COI. Disclosed dollar amounts will not be published or reported within ATS conferences or projects or otherwise reported by ATS to the public. Disclosers employed by commercial enterprises or non-profit institutions must report their employment as a financial interest but are not required to disclose his/her compensation from employment, with exception of self-employed independent contractors whose proceeds from work relevant to activity subject matter should be reported (e.g., if the person's work is as an independent contractor providing services to commercial entities, each commercial entity involved and the total payments received from each entity should be reported).
- Disclosure of relationships with manufacturers or marketers of products or processes thought to cause respiratory disease or disorders, including specifically: manufacturers or marketers of tobacco products, vaping products, and cannabis products consumable by inhalation, or their subsidiaries. Consistent with the ATS Policy Governing Relationships Between the Tobacco Industry, ATS Members and Non-Members who Participate in ATS Activities and the ATS Policy on Association with the Cannabis Industry, all relationships with tobacco, vaping, and cannabis entities, as defined by these policies, that have existed at any point during the person's professional career must be disclosed.
- Attestation by the discloser that they are familiar with the ATS <u>Policy Regarding</u>
  <u>Professionalism and Ethical Conduct</u> and have and will behave in official ATS
  activities consistent with it. (See page 12 for link to that policy.)

## ii. Review and Mitigation of Participant COI:

a) Authorized staff and members, including but not limited to members of the Ethics and Conflict of Interest Committee, the ATS Documents Editor for official ATS documents, and the respective ATS Journal Editors and associate editors, shall review in confidence the disclosed financial interests and other conflicts reported for persons under consideration for ATS official roles, such as governance roles, developers of clinical practice guidelines, and Journal manuscript authorship. Reviewers shall receive instructions that clearly articulate procedures for review, determination, and mitigation of identified COI. If a relevant conflict of interest is identified, those responsible for approving the person's participation shall be informed and shall help to ensure appropriate mitigation (resolution) occurs before the person's official role begins, using

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Version 10, effective January 1, 2022

#### Page 7 (of 12)

mitigation methods approved by the ATS and consistent with relevant standards, such as the requirements of the ACCME for CME activities.

- b) ATS staff and other designated COI reviewers, overseen by the Ethics and Conflict of Interest Committee, should ensure that all required procedures have been followed and that decisions made during the review and mitigation process are consistent with ATS policies.
- c) Examples of recommended procedures for COI review and mitigation within relevant ATS activities are:
  - For candidates for ATS office: the ATS Nominating Committee should receive and review COI disclosures from individuals under consideration as nominees for office and should consider identified COIs and whether they are resolvable using ATS approved methods disclosure or recusal alone or require additional consideration. The COI disclosures of candidates for Assembly Chair, other potential members of the ATS Board of Directors, and members of President-appointed committees should also be reviewed by authorized staff and members, and the respective Nominating Committee or appointing officer informed of the results and any mitigation necessary before the person's election or appointment.
  - For candidates for project/conference chair or organizer: authorized staff and members should review the persons' COI disclosures in relation to project/conference subject matter and inform those responsible for approval of the person's service as chair or organizer, so that they are able to help to ensure appropriate mitigation (resolution) occurs before the person's official role begins.
  - For project or conference participants: assigned staff and ATS-designated COI reviewers will review the disclosures of prospective participants (e.g., members of project committees and planners and presenters of workshops and conferences), and it may be necessary to limit a person's involvement if it is concluded that a COI isn't resolvable. Written documentation of the review, including any COI identified and recommendations for mitigation (if approved by ATS) shall be submitted to designated ATS staff and provided by staff to the project chair or conference chair.
  - For official ATS documents, e.g., clinical practice guidelines:

Review and mitigation of participants in the writing of official ATS documents shall be consistent with procedures established by the ATS Documents Editor in consultation with ATS-designated COI staff and the Ethics and Conflict of Interest Committee. The process used may differ from those of other activities to be consistent with standards for clinical practice guidelines and other official documents. (See ATS *Policy for Management of Financial Conflicts of Interest in the Development of ATS Clinical Practice Guidelines*, linked to page 12 of this policy.)

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Version 10, effective January 1, 2022

#### Page 8 (of 12)

• For key ATS staff: disclosure of COI should be required of key 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.

## iv. Maintenance of Currency and Completeness of Disclosures on File:

The person disclosing should review his/her disclosures on file with the ATS, and available to the person online, at least annually and each time that disclosure for an official activity is requested by ATS. Any new financial interests or developments that might influence or be thought to influence an individual's participation in an official ATS activity must be disclosed by the individual by updating his/her most recent disclosure form on file. New financial interests or developments relevant to the subject matter of the official activity should also be brought to the attention of decision makers within the activity (e.g., project/conference chairs, organizing or writing committee members, conference session faculty), such as by oral disclosure at the next meeting.

# v. Disclosure of COI to Participants and Audiences of Official Activities, including CME Learners:

Relevant disclosures of persons in official ATS activities shall be provided to participants and audiences of the official ATS activities where disclosure is required. For example: the COI of authors/contributors of official ATS documents such as clinical practice guidelines shall be published within the document; CME planner and presenter COI should be reported to CME learners consistent with ACCME requirements; members of committees developing official documents, such as clinical practice guidelines, or committees appointed by the ATS President, should ensure that in addition to disclosure to ATS by the online disclosure process, each participant (e.g., committee member) informs or reminds the Committee chair and participants by oral disclosure of any financial interests and/or other COI relevant to a topic before discussion of the topic begins and related conclusions or recommendations made.

If the ATS earlier determined that the COI noted in oral disclosure during a committee's deliberations warrants having the person recuse from relevant discussions and/or conclusions or recommendations of the committee, or if the COI is new and hadn't yet been disclosed to the ATS and reviewed and mitigated by it, the respective activity chair may to ask the person to recuse. Guidance on recusal as mitigation should be provided to activity chairs before the activity. Explanations of the processes used to identify and resolve COI should also be made available to committee members and activity audiences, e.g., for official documents by inclusion in the document's methods section, of official documents and on the ATS website.

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Version 10, effective January 1, 2022

Page 9 (of 12)

## vi. Involvement of Industry-Employed Members and Other Industry Employees:

ATS members and other healthcare professionals and scientists employed by or affiliated with the pharmaceutical or medical device industries, or other industries relevant to ATS interests, make important and often unique contributions to the ATS mission, and with few exceptions shall be welcomed throughout the Society.

The business interests of the employer of an industry-employed member, or another industry employee involved in an ATS activity, can by their nature cause or be thought to cause a COI that could affect the independence of the activity. Accreditors such as the Accreditation Council for Continuing Medical Education (ACCME) and other standard-setting organizations such as the Council of Medical Specialty Societies (CMSS) require the ATS to carefully manage the involvement of industry-employed persons in certain roles to ensure that activities can be seen as free of commercial bias. Examples of restricted roles include the planning and presentation of content in accredited continuing medical education activities (which is not permitted for industry employees except when certain conditions are met <sup>2</sup>), the development of clinical practice guidelines, and service as a Journal Editor or Society officer. ATS manages these and other activities accordingly. ATS also prohibits or strictly limits participation by employees of tobacco companies and their subsidiaries and companies that manufacture and market inhaled cannabis products.<sup>1</sup>

Industry-employed members and other industry employees are welcome and encouraged to participate fully in Society activities including attending ATS conferences and contributing to non-CME scientific exchange such as presentation of abstracts and posters and submission of manuscripts to ATS journals. Industry-employed members are welcome to serve on ATS President-appointed committees and Assembly committees when appointed, with exception of committees involved in the planning of ATS CME activities, which are subject to ACCME restrictions. All industry-employed members and other industry employees participating in these programs should contribute to a high degree of transparency regarding their commercial interests and disclose these to the ATS and the audience. At times participants may be asked to recuse or should consider recusing from decision-making directly relevant to their employer's business interests.

Information for industry-employed members and other industry employees regarding any special considerations or limitations related to involvement in ATS activities should be made available on the ATS website and other targeted communications, as should information on ATS activities for which their involvement in scientific exchange and knowledge of general industry practices is especially sought and welcome.

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Version 10, effective January 1, 2022

Page 10 (of 12)

## vii. Relationships with the Tobacco Industry, Vaping Industry, and Cannabis Industry

The ATS has enacted a *Policy Governing Relationships Between the Tobacco Industry*, ATS Members and Non-Members who Participate in ATS Activities and a Policy on Association with the Cannabis Industry. The policies regard relationships held at any point of person's professional career with tobacco entities and subsidiaries, vaping entities, and cannabis entities (as defined within the policies) as a conflict of interest that must be disclosed to the ATS before a person's participation in an official ATS capacity. Existing or recent relationships with tobacco entities and subsidiaries and manufacturers and marketers of inhaled cannabis products make a person ineligible for official ATS roles, such as service in governance roles; publication in ATS journals; planning and presenting at the ATS International Conference or other ATS CME activities; service on a writing committee of an ATS clinical practice guideline or other official document; service as a ATS journal editor or journal reviewer; and recipient of ATS recognition awards. The *Policy Governing Relationships Between the Tobacco* Industry, ATS Members and Non-Members who Participate in ATS Activities and the Policy on Association with the Cannabis Industry will be treated as procedural appendices to this general policy. (See page 12 for links to these policies.)

## viii. CMSS Code for Interaction with Companies:

The ATS has endorsed the *Code for Interaction with Companies* of the Council of Medical Specialty Societies, a voluntary code of conduct for Medical Specialty Societies to enhance professionalism and to disclose, manage and resolve relationships with industry. Topics addressed by the Code include independence, transparency, accepting charitable contributions, accepting corporate sponsorships, society meetings, awarding of research grants, clinical practice guidelines, society journals, standards for advertising, and standards for licensing. The Code will be treated as a procedural appendix to this policy. (See page 12 for links to these policies.)

## ix. ATS Policy on Professionalism and Ethical Conduct:

The ATS has enacted a *Policy Related to Professionalism and Ethical Conduct* that requires that all those participating in official ATS activities uphold the highest standards of professionalism and ethical conduct. Among other provisions, that Policy states that "Any volunteer (whether a member of ATS or not) in an official ATS role, or proposed to ATS to do so, may be declared by ATS staff leadership and/or the Ethics Committee to be ineligible for that role pursuant to applicable conflicts of interest policies, in accordance with policies and procedures adopted by the Board of Directors from time to time." The Professionalism and Ethical Conduct policy will be treated as a procedural appendix to this policy. (See page 12 for link to that policy.)

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Version 10, effective January 1, 2022

Page 11 (of 12)

## VI. POLICY OVERSIGHT AND ADJUDICATION:

- A. The Ethics and Conflict of Interest Committee shall oversee the ATS procedures and instruments used to disclose, review, and mitigate COI. The Committee shall advise ATS leaders and activity participants (especially the chairs and other persons in control of official ATS activities), in COI matters relevant to their responsibilities and the ATS mission. Appropriate ATS staff shall be made available to implement ATS COI policies and procedures and assist members and others throughout the COI management process.
- B. The ATS *Policy Related to Professionalism and Ethical Conduct* also addresses oversight and adjudication responsibilities of the Ethics and Conflict of Interest regarding COI policy violations by members and others, by stating among other provisions:
  - Any member may be subject to reprimand by a two-thirds vote of the Committee on Ethics and Conflict of Interest ("Ethics Committee") for violation of applicable conduct or conflicts of interest policies, in accordance with policies and procedures adopted by the Board of Directors from time to time. The Ethics Committee may, upon a two-thirds vote, recommend other discipline, including suspension or expulsion, to the Executive Committee, which shall have the authority to impose any discipline by a two-thirds vote.
  - Any volunteer (whether a member of ATS or not) in an official ATS role, or proposed to ATS to do so, may be declared by ATS staff leadership and/or the Ethics Committee to be ineligible for that role pursuant to applicable conflicts of interest policies, in accordance with policies and procedures adopted by the Board of Directors from time to time.
- C. In instances where determination of COI and the actions taken to resolve COI in official ATS activities has been disputed, the Ethics and Conflict of Interest Committee and its staff shall adjudicate matters when needed, subject to the review and approval of the ATS Executive Committee, and with consultation of other ATS stakeholders relevant to the matter. Examples of stakeholders include but are not limited to the following: the Board of Directors; ATS staff leaders; the Documents Editor and leaders or representatives of the Documents Development and Implementation Committee and its staff; Journals editors, associate editors, and editorial staff; the Education Committee and its staff; the International Conference and its staff, the Council of Chapter Representatives and its staff; Assembly leaders and assembly programs staff, and key leaders including the Executive Committee and Board of Directors. The Ethics and Conflict of Interest Committee and its staff shall also advise and be in dialogue with the ATS Drug and Device Discovery Committee and its staff regarding ATS COI matters related to industry.
- D. ATS implementation of this policy may occasionally be modified in event of joint activities with organizations whose conflict-of-interest policies differ. In such cases, compliance with this policy and related ATS COI policies (i.e., addressing specific areas such as clinical practice guidelines, relationships with the tobacco industry and the cannabis industry,

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Version 10, effective January 1, 2022

## Page 12 (of 12)

patient and family education, and ethical conduct and professionalism in ATS activities), as well as with the Council of Medical Specialty Societies *Code for Interaction with Companies*, will be sought first.

## **Related Policies and Procedures**

- COI Policy for Clinical Practice Guidelines
- COI Policy for Patient and Family Education
- Policy on Association with the Cannabis Industry
- Policy on Tobacco Involvement
- ATS Policy Related to Professionalism and Ethical Conduct
- Council of Medical Specialty Societies (CMSS) Code on Interaction with Companies
- ACCME Standards for Integrity and Independence in Accredited Continuing Education: https://accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce
- ATS COI Disclosure Procedures