

American Thoracic Society International Conference

SUMMARY AND DEFINITIONS OF ATS POLICIES ON CONFLICT OF INTEREST AND TOBACCO INDUSTRY RELATIONSHIPS

Please note: this document is intended as an optional resource for Conference organizers, chairs and presenters, as a summary of information made available on the ATS COI Website and ATS Website. If you have questions about ATS COI policies, please contact Shane McDermott, Senior Director, Ethics & Conflict of Interest Management at smcdermott@thoracic.org or 212-315-8650.

INTRODUCTION

Procedures for disclosure and management of conflicts of interest (COI) of Conference session chairs/organizers and presenters comply with the following policies:

- the **Policy on Management of Conflict of Interest in Official ATS Documents, Projects and Conferences** (ATS Policy on Management of COI), as approved by the ATS Board of Directors in March 2008;
- the **Policy Governing Relationships Between the Tobacco Industry, ATS Members, and Non-Members Who Participate in ATS Activities** (ATS Tobacco Relationships Policy), as amended by the ATS Board of Directors in December 2007;
- and the requirements of the **Accreditation Council for Continuing Medical Education** (ACCME) and **American Medical Association** for accredited providers of continuing medical education (CME) and for awarding of category 1 AMA PRA credit.

PROCESS

The ATS International Conferences disclosure process will:

- (a) Require all who submit a session or course proposal (as part of the **Call for Input** process) and all abstract applicants to answer a limited number of disclosure questions as part of their initial application, which will be reviewed by appropriate ATS reviewers.
- (b) Require all chairs and presenters of approved sessions, once selected, to complete a **more extensive COI disclosure and management process**, including (i) disclosure of COI in all areas noted above, (ii) review of disclosures by appropriate ATS reviewers*, and (iii) management (or “resolution”) of identified COI according to ATS guidelines*.

** Detailed instructions and guidelines for review and resolution of conflicts of interest will be made available to the chairs of approved sessions subsequent to approval.*

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DEFINITIONS:

The following summary is drawn from the ATS Policy on Management of COI and the ATS Tobacco Relationships Policy:

- 1) **Conflict of interest (COI)** is defined by the ATS Policy on Management of Conflict of Interest 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 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 project proposal objectively due to competition for funding, timing of publication or professional stature.
- 2) **“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.

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3) The tobacco industry and individual tobacco companies (hereinafter called **tobacco entity**) are **defined as** including the following:

(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.

4) ATS policy requires disclosure of personal financial interests of your **spouse, life partner, and dependents**, if the financial interest is known to you, in addition to your own.

5) However, **specific to tobacco relationships**, the ATS tobacco relationships policy requires disclosure of relationships of **spouse or life partner**, in addition to those of the individual. The policy also states: "A spouse or life partner's relationship with the tobacco industry or stock/option ownership will not be considered a relationship of the individual with the tobacco industry nor will it be considered as grounds for automatic limitations on the individual's participation in ATS activities specified in this policy."

6) Examples of **activities that define a relationship with a tobacco entity** for an ATS member or non-member who participates in ATS-sponsored activities (both hereinafter called "individual") include but are not limited to the following: (1) Employment of the individual by a tobacco entity; (2) Consultancy by the individual with a tobacco entity; (3) Board or Advisory Board service of the individual with a tobacco entity; (4) Lecture fees (honoraria) paid to the individual by a tobacco entity; (5) Expert witness by the individual on behalf of a tobacco entity; (6) Testimony by the individual on a legislative or regulatory matter on behalf of a tobacco entity; (7) Receipt or pending receipt by the individual of a tobacco entity-sponsored grant including contracted research; (8) Receipt or pending receipt by the individual of patents from a tobacco entity; (9) Receipt or pending receipt by the individual of royalties from a tobacco entity.

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DISCLOSURE REQUIREMENTS:

1) **ATS requires** disclosure of 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. This includes:

- disclosure of any direct financial benefit derived from work performed for industry (per company), or any direct financial interest or investment in industry (per company);
- disclosure of whether or not the individual has received support from a non-commercial (non-profit) source that has an interest in official activities of the ATS (e.g., a government, foundation, or other nonprofit source);
- and 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. The individual is not required to make specific inquiries of the authorities of his/her institution.

2) **In addition, specific to relationships with tobacco entities**, per the ATS policy on tobacco relationships, individuals must disclose any present or past relationships with a tobacco entity 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 their spouse or life partner. A spouse or life partner's relationship with the tobacco industry or stock/option ownership will not be considered a relationship of the individual with the tobacco industry nor will it be considered as grounds for automatic limitations on the individual's participation in ATS activities specified in this policy.

3) **Note:** the **ATS definition of conflict of interest conforms with and exceeds the current ACCME definition:**

- The ACCME requires disclosure of “relationships with a commercial interest if both (a) the relationship is financial and occurred within the past 12 months, and (b) the individual has the opportunity to affect the content of CME about the products or services of that commercial interest.”
- The ACCME defines a commercial interest as “any proprietary entity producing health care goods or services consumed by or used on patients”. The ACCME doesn't consider providers of clinical service directly to patients to be commercial interests.

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- The ACCME defines financial relationships (with a commercial interest) as those “relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g. stocks, stock options or other ownership interest, excluding diversified mutual funds) or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities for which remuneration is received or expected.”
- The ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.
- The ACCME has not set a minimum dollar amount for relationships to be significant, and maintains that “inherent in any amount is the incentive to maintain or increase the value of the relationship.”

FOR MORE INFORMATION:

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