



American  
Association of  
Neurological  
Surgeons

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## UPDATED STANDARDS FOR MANAGING CONFLICTS OF INTEREST IN EDUCATIONAL ACTIVITIES

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## I. BACKGROUND INFORMATION

The AANS CME program aims to develop, maintain, and increase the competency, skills, and/or performance of neurosurgical healthcare professionals by providing high quality, relevant, accessible and cost-effective educational activities. AANS is committed to innovation in education. AANS CME activities are responsive to the identified education needs of the participants and support their lifelong learning on behalf of improving patient care.

The AANS recognizes that there are a variety of financial relationships between individuals and commercial interests that require review to identify possible conflicts of interest in a CME activity. This policy is designed to ensure quality, objective, balanced, and scientifically rigorous AANS directly sponsored or jointly sponsored Continuing Medical Education (CME) activities by identifying and resolving all potential conflicts of interest prior to the confirmation of service of those in a position to influence and/or control CME content.

All AANS CME activities will adhere to the *2004 Updated Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support: Standards to Ensure the Independence of CME Activities*. In accordance with these Standards, the following decisions will be made free of the control of a commercial interest: identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content, selection of educational methods, and evaluation of the CME activity (ACCME Standard 1.1).

The purpose of this policy and its associated procedures is to ensure all potential conflicts of interest are identified and mechanisms to resolve them prior to participation in the planning and/or presenting of CME activities are implemented in ways that are consistent with the public good.

## II. POLICY TO IDENTIFY AND RESOLVE CONFLICTS OF INTEREST

The ACCME requires accredited CME providers to identify **and resolve** all potential conflicts of interest with any individual in a position to influence and/or control the content of CME activities. A potential conflict of interest will be considered to exist if the individual has received financial benefits in any amount from a commercial interest within the past 12 months AND that individual is in a position to affect the content of CME regarding the products or services of the commercial interest. This policy will be communicated to all individuals in a position to influence and/or control the content of AANS directly and jointly sponsored CME activities either prior to their appointment on a planning committee or prior to the activity taking place.

As a CME provider accredited by the ACCME, the AANS requires all individuals (and their significant others) in a position to influence and/or control the content of AANS directly and jointly sponsored CME activities to disclose to the AANS and subsequently to learners that the individual either has **no relevant financial relationships** or has **any relevant financial relationships** with a commercial interest. Individuals are required to disclose the following information per ACCME Standard 6.1 (see appendix A):

- name of the individual
- name of the commercial interest(s)
- nature of the financial relationship the individual has with each commercial interest

“Disclosure” must never include the use of a trade name or a product-group message (ACCME Standard 6.4). All disclosure information must be provided to AANS CME activity participants prior to the beginning of the CME activity (ACCME Standard 6.5).

All potential conflicts of interest identified through review of the disclosure form must be resolved in order for individuals in a position to influence and/or control CME content to be confirmed for the

educational assignment. The resolution process and outcomes must be documented in the CME activity file.

The AANS requires that the content of directly and jointly sponsored CME activities provide balance, independence, objectivity, and scientific rigor. Planning must be free of the influence or control of a commercial entity, and promote improvements or quality in healthcare. In addition, the content or format of a CME activity and its related materials must promote improvements or quality in healthcare and not a specific proprietary commercial interest (ACCME Standard 5.1). All AANS CME activities must be compliant with the ACCME content validation statements:

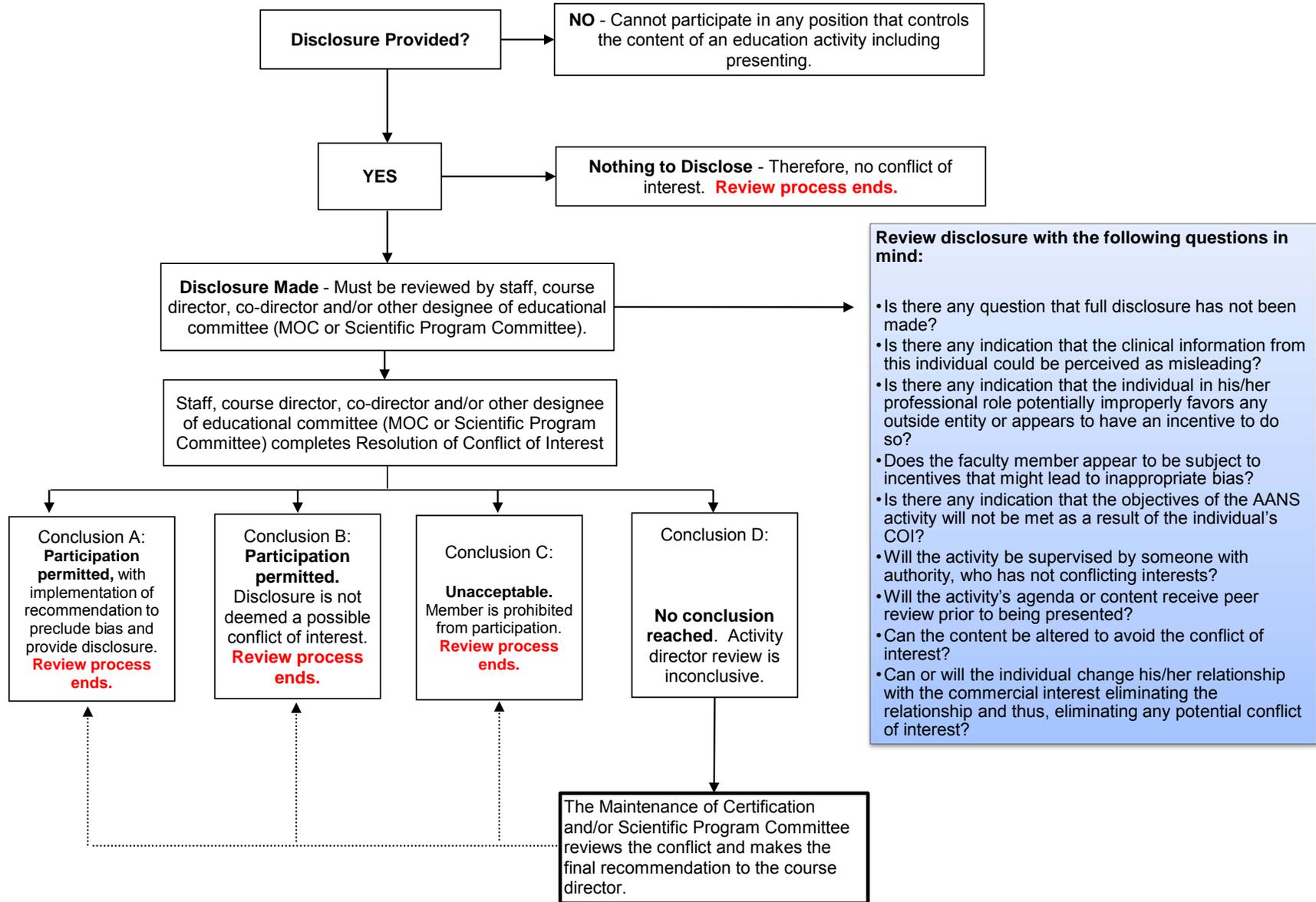
- All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
- All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.
- Providers are not eligible for ACCME accreditation or reaccreditation if they present activities that promote recommendations, treatment or manners of practicing medicine that are not within the definition of CME, or known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients.

Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, trade names from several companies should be used and not just trade names from a single company (ACCME Standard 5.2). Educational materials that are part of a CME activity such as slides, abstracts, and handouts cannot contain any advertising, trade names without generic names (but listing of trade names from several companies is permissible), or product-group advertising (ACCME Standard 4.3).

Any individual refusing to comply with this policy and/or not disclosing relevant financial relationships on a timely basis (**DEFINED AS THE INITIAL INVITATION AND TWO REMINDERS**) will not participate in, have control of, or responsibility for, the development, management, presentation, or evaluation of AANS CME activities.

All AANS CME activities will be evaluated by learners and possibly by peer reviewers to determine if the content was free of commercial bias. All those identified as having influence and/or control of CME content perceived as either manifesting conflicts of interest or being biased may be disqualified from consideration as resources (planning group member, authors, faculty, etc) in subsequent CME activities.

### III. FLOWCHART SUMMARY OF AANS PROCESS TO RESOLVE CONFLICTS OF INTEREST



#### IV. FORM TO EVALUATE AND DOCUMENT RESOLUTION OF CONFLICT OF INTEREST



### RESOLUTION OF CONFLICT OF INTEREST FORM

#### For AANS CME Activities

The *Resolution of Conflict of Interest Form* is designed to assist AANS staff and volunteer physician leaders responsible for the development of CME activities in 1) determining if a conflict of interest exists; and 2) documenting the actions undertaken to resolve all potential conflicts of interest with any individual in a position to influence and/or control the content of CME activities. **This form must be completed for all individuals returning a disclosure listing financial relationships with commercial interests.** There are a variety of mechanisms available to resolve a potential conflict of interest and those completing this form are asked to review the following list below to determine if any of these mechanisms are adequate in resolving a specific conflict. Once that determination is made, the mechanism(s) used to resolve the conflict must be documented. If there remains a conflict of interest that cannot be resolved, that should be documented as well. This form should then be inserted in the appropriate CME activity file that includes all documentation to ensure compliance with ACCME Essentials, Elements, and Standards.

#### **PLEASE COMPLETE THE FOLLOWING:**

NAME OF INDIVIDUAL WITH THE EDUCATIONAL ASSIGNMENT:

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NATURE OF THE EDUCATIONAL ASSIGNMENT:

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(eg, CME planning group member, author, faculty, etc)

NAME OF THE CME ACTIVITY (DATES/LOCATION IF APPLICABLE)

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NAME OF INDIVIDUAL SUBMITTING THIS FORM:

\_\_\_\_\_ DATE \_\_\_\_\_

Signature: \_\_\_\_\_

\_\_\_ **Upon review of the disclosure form it was determined that the financial relationship does not relate to the educational assignment. IF SO, YOUR FORM IS NOW COMPLETE.**

#### **OR IF NOT, PLEASE PROCEED**

**Upon review of the disclosure form, it was determined that a potential conflict may exist and the following mechanism(s) were used to resolve that potential conflict of interest:**

1. \_\_\_ **We used a peer review process\* for enduring material CME (including online), live activity, journal CME, etc.** (process by which materials are peer reviewed or judged to ensure the data support the conclusions before they are accepted for Presentation or publication). If necessary, faculty will be required to revise content based on recommendations from the peer review.

2.  **Based on previous history with this individual, I can attest that no commercial bias exists in his/her presentation.** The presentation has been evaluated in the past and no commercial bias was detected.
  
3.  **We altered the control over the content by:**
  - choosing someone else to control that part of the content
  - changing the focus of the CME activity so that it does not relate to the products or services of the commercial interest
  - changing the content/topic of the individual's educational assignment so that it does not relate to the products or services of the commercial interest
  - limiting the individual's content to a report without practice recommendations (if individual was funded by a commercial company to perform research, the individual's presentation may be limited to research data and results)
  - limiting the role of the individual to reporting practice recommendations based on formal structured review of the literature with the inclusion and exclusion criteria stated (evidence-based)
  - other (please describe)
  
4.  **The individual was able to document the 'best available evidence' to support his/her recommendations. (eg, individual provided adequate references)**  
 (Suggestion: The individual may state to the learners, "the best available evidence in the literature is at the level of < > and supports the following conclusions < >. Integrating what this literature says with what the new study has revealed, my recommendations on what we should do now are < >".
  
5.  **The individual decided to change his/her relationship with the commercial interest, eliminating the financial relationship and thus, any potential for conflict of interest.**
  
6.  **We chose not to use the individual and identified a replacement.**
  
7.  **Other (please describe)**

\*Peer review must ensure that 1) all practice recommendations involving clinical medicine are based on evidence that is accepted within the profession of medicine as adequate justification for indications and contraindications in the care of patients; and 2) all scientific research referred to, reported or used in the CME activity in support or justification of patient care recommendations conforms to the generally accepted standards of experimental design, data collection and analysis.

**INSERT IN CME ACTIVITY FILE**

## V. MECHANISM TO MANAGE FACULTY WHO VIOLATE STANDARDS

As stated in the *Policy to Identify and Resolve Conflicts Of Interest* section, all AANS CME activities will be evaluated by learners and possibly peer reviewers to determine if the content was free of commercial bias. All those identified as having influence and/or control of CME content perceived as either manifesting conflicts of interest or being biased may be disqualified from consideration as resources (planning group member, authors, faculty, etc) in subsequent CME activities. Step-by-step instructions are included below:

- Step 1:** Staff conducts an evaluation of the CME activity to, among other things, determine the perception of commercial bias. All AANS CME activities must include a mechanism for evaluating the perception of commercial bias (eg, inclusion of a question on the attendee evaluation form of the activity and/or faculty; inclusion of a question on the monitor evaluation form of the activity and/or faculty, etc.)
- Staff may request that there is a peer monitoring of that activity (see form in Appendix B). The peer reviewer will be asked to complete an evaluation form measuring any bias in the CME activity. (**NOTE:** Consider the use of residents as monitors and preferably those not involved in the planning.)
- Step 2:** Staff reviews evaluation data to assess perception of commercial bias in the CME activity.
- Step 3:** Staff documents these findings along with any additional documentation related to the assessment of the evaluation data in the CME activity file and communicates this information to the course director and/or planning committee.
- Step 4:** Any concerns as a result of the evaluation data should be handled accordingly including disqualification in future CME activities. Each violation will be considered on a case-by-case basis.

## APPENDIX A: STEPS FOR ONLINE DISCLOSURES

1. Login to MyAANS.org. This disclosure form is now linked to **all** AANS speaking engagements/committee positions. Therefore, disclose all relevant financial relationships only once per year or as needed should your disclosure change.
2. Click on Disclosure on the far left.
3. If you do not have any disclosure, please click the button next to, “**I do NOT have any financial relationships with any commercial interests.**”
4. If you have a disclosure, please click the button next to, “**I DO have financial relationships with commercial interests which I will disclose below.**”

<p><a href="#">Home</a> <a href="#">Comments &amp; Suggestions</a> <a href="#">Profile</a> <a href="#">Census</a> <a href="#">Balloting</a> <a href="#">CME</a>     <a href="#">CME Affiliations</a>     <a href="#">CME Test Editor</a>     <a href="#">Self Reporting</a>     <a href="#">Residency Program</a> <a href="#">Committees</a> <a href="#">Directory</a> <a href="#">Disclosure</a> <a href="#">Exhibitor's Corner</a> <a href="#">Member Applications</a> <a href="#">Online Payments</a> <a href="#">Online Case Studies</a>     <a href="#">Help</a> <a href="#">Resources</a>     <a href="#">Member Media Kit</a> <a href="#">Speaker's Corner</a></p>	<h3>Disclosure Statement</h3> <p style="text-align: right;">Last Updated: <b>7/21/06</b></p> <p>ACCME's Updated Standards for Commercial Support requires that anyone in a position to control the content of the education activity has disclosed all financial relationships with any commercial interest (see Glossary Terms below). Failure or refusal to disclose or the inability to satisfactorily resolve the identified conflict may result in the withdrawal of the invitation to participate in any AANS education activities.</p> <hr/> <p>This disclosure form is now linked to <b>all</b> AANS speaking engagements. Therefore, disclose all relevant financial relationships only once, not per engagement.</p> <hr/> <p>Please indicate your financial relationships by checking the appropriate box below: (PLEASE NOTE: This disclosure is valid for 12 months...please update as needed)</p> <p><input type="radio"/> <b>I do NOT have any financial relationships with any commercial interests.</b></p> <p><input checked="" type="radio"/> <b>I DO have financial relationships with commercial interests which I will disclose below..</b></p> <ul style="list-style-type: none"><li>■ List the names of proprietary entities producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies with which you or your spouse/partner or your co-author have, or have had, a financial relationship within the past 12 months. For the purpose of this disclosure, ACCME considers the financial relationships of your spouse/partner and/or your co-authors to be included as yours.</li><li>■ Clarify what you or your spouse/partner and/or co-author received (ex: salary, honorarium, stock, etc) specify the company name next to your role with the company below.</li></ul> <p style="text-align: center;"><b>Corporate Organization Affiliation / Financial Interest</b></p> <table border="0" style="width: 100%;"><tr><td style="background-color: #cccccc; height: 15px; width: 80%;"></td><td style="text-align: right;"><a href="#">Add</a></td></tr><tr><td style="background-color: #cccccc; height: 15px;"></td><td style="text-align: right;"><a href="#">Add</a></td></tr></table> <p style="text-align: center;"><a href="#">Submit</a></p>		<a href="#">Add</a>														
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5. Please click on **Add** to enter a disclosure. Each one will need to be entered separately.

I hereby certify that the information I reported in this disclosure is current and correct.

6. Once completed, you must click on the blue submit button or all information entered will be lost.

**APPENDIX B: PEER REVIEW FORM**



**ON-SITE PEER REVIEW**

Course Name:

Location:

Date of Course:

Course Director:

Reviewer:

Date of Review:

1. Were there company logos on any of the presentation slides during the CME activity? This does not include logos for their practice or academic institution. Yes  No

If yes, who was presenting and what company logo was shown: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

2. Were company brochures or literature distributed in the CME activity room (the room in which the actual meeting was held)? Yes  No

If yes, please explain: \_\_\_\_\_

\_\_\_\_\_

3. Exhibits:
- a. Were in the same meeting room as the CME activity, but were separated by an air wall or curtain.
  - b. Were in the same meeting room as the CME activity with no separation from the CME activity space.
  - c. Were in a separate room.
  - d. There were no exhibits at this CME activity.

4. Commercial bias is defined by the Accreditation Council for Continuing Medical Education (ACCME) as a personal judgment in favor of specific proprietary business of a commercial interest. A **commercial interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The following types of organizations **are not** considered to be commercial interests by the ACCME definition:

501-C Non-Profit Organization	Government Organizations	For-Profit Hospitals
Non-Health Care Related Companies	Liability Insurance Providers	For-Profit Nursing Homes
Health Insurance Providers	Group Medical Practices	For-Profit Rehabilitation Centers

Did you perceive any type of commercial bias during this program? Yes  No

If yes, please explain. What was perceived as promotional and not educational? (Please include faculty name/presentation title)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature

Date

## **APPENDIX C: GLOSSARY OF TERMS**

### **Individuals in a position to influence and or control CME content**

The AANS has defined these as follows: faculty (live and online courses); authors and co-authors of journal CME articles, Neurosurgical Focus articles, self-assessment exercises, enduring materials (eg. CD ROM, video, books, online courses, etc.) and abstracts; CME planning groups/committees/commissions; CME editorial boards, CME article peer reviewers; staff serving as CME faculty and those directly impacting CME content; the significant others of those mentioned.

### **Commercial Bias**

A personal judgment in favor of a specific proprietary business interest of a commercial interest.

### **Commercial Interest**

A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The following are not considered to be a commercial interest and therefore do not have to be disclosed:

501-C Non-profit organizations*	Government organizations	Non-health care related companies
Liability insurance providers	Health insurance providers	Group medical practices
For-profit hospitals	For profit rehabilitation centers	For-profit nursing homes
Blood banks	Diagnostic laboratories	

*\*Note: ACCME screens 501c organizations for eligibility. Those that advocate for 'commercial interests' as a 501c organization are not eligible for accreditation in the ACCME system. They cannot serve in the role of joint sponsor, but they can be a commercial supporter.*

### **Financial relationships**

Financial relationships are 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 benefits. 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 from which remuneration is received or expected. A personal financial relationship does NOT exist when a company contracts with an institution to perform research and the institution then independently employs individuals to work on the institution's project.

**ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse or partner.**

\* "Contracted research" includes research funding where the institution obtains the grant and manages the funds and the individual is the principal or named investigator on the grant.

### **Relevant financial relationships**

ACCME focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME defines "relevant financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

### **Conflict of Interest**

Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has financial relationship.

### **What creates a conflict of interest?**

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both:

1. A financial relationship with a commercial interest and
2. The opportunity to affect the content of CME about the products or services of that commercial interest. The ACCME considers "content of CME about the products or services of that commercial interest" to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.