

GUIDELINES FOR INTERACTION WITH COMMERCIAL ENTERPRISES AND
MEDICAL INDUSTRY FOR THE CONGRESS OF NEUROLOGICAL SURGEONS
(CNS), CNS MEMBERS, AND CNS PUBLICATIONS
2008

PREAMBLE

The Congress of Neurological Surgeons (CNS) exists for the purpose of promoting the public welfare through the advancement of neurosurgery, by a commitment to excellence in education, and by dedication to research and scientific knowledge. It is implicit in that purpose that each member of the CNS whether acting as a practitioner, educator, author or editor ascribes to the highest ethical standards. As such the purpose of these Guidelines is to describe appropriate behavior for CNS members in three (3) separate roles when commercial support is involved: CNS member relationships with their patients; planning, designing, implementing, and evaluating CNS educational activities; and authoring or editing of CNS sponsored publications.

SCOPE OF GUIDELINES

It is acknowledged that the CNS membership and Commercial Interests may interact on many levels. These include research and programs for the advancement of medical technology, instruction on the safe and effective use of technology, education projects, consultation, conference support, and publication of scientific or educational material. The activities of the Joint Sections of the AANS/CNS are considered under the umbrella of the CNS parent, and in this document will be considered under the CNS moniker.

These Guidelines apply to all CNS members, CME activities, and CNS sponsored publications. Commercial Support is defined as financial, or in-kind, contributions given by a commercial interest, which is used to pay all or part of the costs of a CME activity. "Commercial interest" includes any proprietary entity producing health care goods or services. Commercial exhibits and advertisements are promotional activities and not continuing medical education. Therefore, monies paid by commercial interests to providers for these promotional activities are not considered to be 'commercial support'. However, accredited providers are expected to use sound fiscal and business practices with respect to promotional activities.

GUIDELINES FOR CNS MEMBERS

GUIDELINE 1: Independence of CNS members

A. All patient care decisions, research activities, or data interpretation should be made free of non-disclosed direct or indirect conflicts of interest.

1. Circumstances create a “Conflict of Interest” when an individual has an opportunity to affect patient care, research activities, or data interpretation about products or services of a commercial interest with which he/she has a relevant financial relationship.

- i. A “relevant financial relationship” is defined by the Accreditation Council for Continuing Medical Education (ACCME) as a financial relationship in any amount occurring within the past 12 months that creates a conflict of interest. A financial relationship is one which the neurosurgeon benefits by receiving a salary, royalty, intellectual property rights (i.e. patent rights), consulting fee, honoraria, ownership interest (i.e. stocks, stock options or other ownership interest excluding diversified mutual funds), gifts, or other financial benefits.
- ii. A “relevant financial relationship” shall be further defined by the CNS according to the amount or “type” of financial benefit conveyed to the neurosurgeon within the past 12 months:
 1. >\$0 - \$1,000 = minimal
 2. >\$1,000 - \$25,000 = minor
 3. >\$25,000 - \$500,000 or 5-50% ownership of a company = major
 4. >\$500,000 or >50% ownership of a company = primary
- iii. Relationships still in a negotiation phase will be classified with the same terminology on the basis of estimated potential future value if the future value is estimated to be >\$10,000.

2. A conflict of interest may also occur when a neurosurgeon or an immediate family member has, directly or indirectly, a financial interest or positional interest or other relationship with industry that could be perceived as influencing the neurosurgeon’s obligation to act in an objective manner.

i. A positional interest occurs when a neurosurgeon or family member is an officer, director, trustee, editorial board member, consultant or employee of a company with which the neurosurgeon has or is considering a transaction or financial arrangement.

GUIDELINE 2: Resolution of Conflicts of Interest for CNS Members

- A. The CNS encourages every CNS member who is in a position to make patient care recommendations or interpret research data disclose as appropriate to the patient, employing institution, the federal government (if required), and/or the CNS all relevant financial relationships with any commercial interest.
- B. A CNS member should implement a mechanism to identify and resolve all conflicts of interest prior to engaging in any patient care or research activity relevant to the conflict of interest. For example, a CNS member with a relevant financial relationship with a commercial interest should formally disclose that relationship to a patient in the event the CNS members has proposed using a product associated with the relevant financial relationship in the care of the patient.
- C. When faced with a potential conflict of interest that cannot be resolved, a neurosurgeon should consult with an institutional or professional society ethics committee to determine whether a conflict of interest exists and how to address it.
- D. CNS members are encouraged to disclose conflicts of interest on the public CNS website (<http://www.neurosurgeon.org/conflictdisclosure>).

GUIDELINES FOR CNS SPONSORED CME ACTIVITIES

GUIDELINE 1: CME activities free of commercial interest control

A. The following CME activities must be made free of the control of a commercial interest:

- i. Identification of CME needs;
- ii. Determination of educational objectives;
- iii. Selection and presentation of content;
- iv. Selection of all persons and organizations that will be in a position to control the content of the CME;
- v. Selection of educational methods;
- vi. Evaluation of the activity.

B. A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

C. All decisions regarding the content of CME activities must be made by individuals who have fully disclosed all conflicts of interest regarding products or services of a commercial interest to be featured in the CME activity.

- i. 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 a relevant financial relationship.
 - a. A “relevant financial relationship” is defined by the ACCME as a financial relationship in any amount occurring within the past 12 months that creates a conflict of interest. A financial relationship is one which the neurosurgeon benefits by receiving a salary, royalty, intellectual property rights (i.e. patent rights), consulting fee, honoraria, ownership interest (i.e. stocks, stock options or other ownership interest excluding diversified mutual funds), gifts, or other financial benefits.
 - i. A “relevant financial relationship” shall be further defined by the CNS according to the amount or “type” of financial benefit conveyed to the neurosurgeon within the past 12 months:
 1. >\$0 - \$1,000 = minimal

2. >\$1,000 - \$25,000 = minor
 3. >\$25,000 - \$500,000 or 5-50% ownership of a company = major
 4. >\$500,000 or >50% ownership of a company = primary
- ii. Relationships still in a negotiation phase will be classified with the same terminology on the basis of estimated potential future value if the estimated future value is >\$10,000.
 - iii. Relationships reported under the above definition (ii or iii) will be subclassified as:
 1. Salary
 2. Consulting Agreement
 3. Royalty
 4. Intellectual Property Fees and Patent Rights
 5. Honoraria
 6. Ownership Interest
 7. Gifts
 8. Other
- b. A conflict of interest may also occur when a neurosurgeon or an immediate family member has, directly or indirectly, a financial interest or positional interest or other relationship with industry that could be perceived as influencing the neurosurgeon's obligation to act in an objective manner on behalf of the CNS.
 - i. A positional interest occurs when a neurosurgeon or family member is an officer, director, trustee, editorial board member, consultant or employee of a company with which the neurosurgeon has or is considering a transaction or financial arrangement.

GUIDELINE 2: Resolution of Personal Conflicts of Interest

A. The CNS must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider.

B. An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

C. The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners. Paper and/or electronic disclosures will be collected for each individual potentially in a position to control the content of an educational activity, prior to the educational activity. Resolution of conflicts will be performed by a group of five people: Chairman of the Compliance and Ethics Committee, Education Committee Chairman, Scientific Program Chairman, Scientific Program Vice Chairman, and CNS Vice President. After review of all relevant information, this group will make a determination regarding the participation of an individual with a potential conflict of interest. A written record of the adjudication and outcome filed with the CNS corporate office and kept on file for seven (7) years.

- i. If a conflict or apparent conflict is noted between a teacher's financial interest and the provider's responsibility to provide unbiased educational material to its learners, the conflict must be resolved to the learner's benefit.

GUIDELINE 3: Appropriate Use of Commercial Support

- A. The CNS must make all decisions regarding the disposition and disbursement of commercial support.
- B. The CNS cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest, as conditions of contributing funds or services.
- C. All commercial support associated with a CNS sponsored CME activity must be given with the full knowledge and approval of the CNS.
 - i. Written agreement documenting terms of support
 - a. The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the CNS and its educational partner(s) (i.e. AANS/CNS Joint Sections). The agreement must include the CNS, even if the support is given directly to the provider's educational partner or a joint sponsor.
 - b. The written agreement must specify the commercial interest that is the source of commercial support.
 - c. Both the commercial supporter and the CNS must sign the written agreement between the commercial supporter and the CNS.

ii. Expenditures for an individual providing CME

- a. The CNS must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.
- b. The CNS, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the CNS's written policies and procedures.
 1. The CNS, the joint sponsor, or designated educational partner may not pay any additional costs associated with the guests of any teacher or author.
- c. No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.
- d. If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

iii.. Expenditures for learners

- a. Social events or meals at CME activities cannot compete with or take precedence over the educational events.
- b. The CNS may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or nonauthor participants of a CME activity. The CNS may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

iv.. Accountability

- a. The CNS must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

GUIDELINE 4. Appropriate Management of Associated Commercial Promotion

- A. Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.
- B. Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.
 - i. For print, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity.
 - ii. For computer based, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content.
 - iii. For audio and video recording, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
 - iv. For live, face-to-face CME, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.
- C. Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message unless the product being discussed is known only by a branded or trade name (e.g. Scotch tape).
- D. Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product promotion material or product-specific advertisement.
- E. The CNS cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

GUIDELINE 5. Content and Format without Commercial Bias

- A. The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.
- B. 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, where available trade names from several companies should be used, not just trade names from a single company.
- C. All analysis of data, manuscript preparation and presentation must be free of commercial input, influence or bias. It will be the work solely of authors and colleagues. Authors will be forthright about disclosing all relevant data. All relevant findings regarding benefits, risks, complications and related issues will be disclosed in all prepared materials.
- D. Teachers and authors must disclose to learners the number and type of relevant financial relationships in the same format their educational material is being presented and in a clear, unambiguous manner. Written material must have conflict of interest disclosures in writing. Audio or visual material must have conflict of interest disclosures in that same format.
 - i. Disclosures of a conflict of interest must include the teacher or author's name, name of the commercial interest, and the type of commercial interest listed as "minimal", "minor", "major" or "primary" as described in Guideline 1C(i)(a)(i and ii) and the subclassification of the relationship as described in Guideline 1C(i)(a)(iii) of this section on CNS sponsored CME activities.

GUIDELINE 6: Disclosures Relevant to Potential Commercial Bias

- A. Relevant financial relationships of those with control over CME content including teachers, authors, providers, volunteer leaders and management staff
 - i. An individual must annually disclose to learners any relevant financial relationship(s), to include the following information:
 - The name of the individual;
 - The name of the commercial interest(s);
 - The nature of the relationship the person has with each commercial interest as "minimal", "minor", "major" or "primary" and subclassification as described in Guideline 1C(i)(a)(1-4).
 - ii. For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

- iii. Disclosure forms will be reviewed by the provider and kept at the CNS corporate office for seven (7) years from the date they are received.

B. Commercial support for the CME activity.

- i. The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.
- ii. 'Disclosure' must never include the use of a trade name or a product-group message.

C. Timing of disclosure

- i. The CNS must disclose the above information to learners prior to the beginning of the educational activity.

CNS POLICIES FOR COMMERCIAL SUPPORT OF CME ACTIVITIES: LUNCHEON SEMINARS AND PRACTICAL COURSES

Information for Course Directors

The purpose of continuing medical education (CME) activities sponsored by the Congress of Neurological Surgeons (CNS) is to enhance the neurosurgeon's ability to care for patients. It is our responsibility to assure that the activity is designed primarily for that purpose.

In the planning and implementation of practical courses and luncheon seminars at the CNS Annual Meeting, we may receive "Commercial Support", which is defined as financial, or in-kind, contributions given by a commercial interest, which is used to pay all or part of the costs of a CME activity. "Commercial interest" includes any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies. While such support can contribute significantly to the quality of the CME program, we must work to ensure that the CME activity is designed primarily to enhance the neurosurgeon's ability to care for patients, and to ensure that the CME activity meets the standards of the ACCME. As a guide for Course Director, the following policies have been adopted:

GUIDELINE I: Independence

When designing your course, the following choices must be made free of the control of a commercial interest:

- Determination of educational objectives;
- Selection and presentation of content;
- Selection of all faculty
- Selection of educational methods

GUIDELINE 2: Resolution of Personal Conflicts of Interest

- A. You and all of the faculty members must disclose all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.
- B. Anyone who refuses to disclose relevant financial relationships will be disqualified from being a course director or faculty member
- C. Your disclosure must be made prior to the CNS Annual Meeting

- D. Faculty disclosures must be made prior to their presentation, preferably prior to the CNS Annual Meeting.
- E. In the case of a potential conflict of interest, the Chair of the CNS Education Committee and/or CNS President, after reviewing all relevant information, will make the final determination as to whether an individual may participate.

GUIDELINE 3: Appropriate Use of Commercial Support

- A. Please check with the CNS office before accepting any type of commercial support. The CNS must ultimately make and approve all decisions regarding the disposition and disbursement of commercial support.
- B. You cannot accept any commercial support if there are “strings attached”. The CNS cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest, as conditions of contributing funds or services.
- C. A commercial entity cannot give any type of support without your permission, and the permission of the CNS. All commercial support must be given with the full knowledge and approval of the CNS.
- D. If your course includes any type of commercial support, make sure that the CNS office has a written agreement with the commercial entity. The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the CNS and its educational partner(s) (i.e. AANS/CNS Joint Sections). The agreement must include the CNS, even if the support is given directly to the provider’s educational partner or a joint sponsor.
- E. Neither you nor your faculty may be paid for their participation, except as allowed by CNS policy.
- F. No commercial entity may pay you or your faculty member directly.
- G. Please communicate with CNS office, especially if there are any questions regarding commercial support. The CNS must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

GUIDELINE 4. Appropriate Management of Associated Commercial Promotion

- A. Advertisements of any kind are prohibited during your course. This includes the time during lectures and “hands-on” demonstrations, as well as in any associated handouts. Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The

juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Promotional activities must be kept separate from CME.

GUIDELINE 5. Content and Format without Commercial Bias

A. Courses must be unbiased. The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest. Presentations must give a balanced view of therapeutic options. Use generic names as much as possible. If your course includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

CONGRESS OF NEUROLOGICAL SURGEONS-PUBLICATIONS: CONFLICT OF INTEREST AND FINANCIAL DISCLOSURES POLICY

GUIDELINE 1: Author Conflicts of Interest and Financial Disclosures.

A. A conflict of interest may exist when an author (or the author's institution or employer) has financial or personal relationships or affiliations that could influence (or bias) the author's decisions, work, or manuscript. All authors are required to disclose all potential conflicts of interest, including specific financial interests and relationships and affiliations (other than those affiliations listed in the title page of the manuscript) relevant to the subject of their manuscript. Authors should err on the side of full disclosure and should contact the editorial office if they have questions or concerns.

B. Disclosures of potential or perceived conflicts of interest including, but not limited to grants, honoraria, ownership interest, stock, employment arrangements or industry relationships that are relevant to the preparation and subject matter of the manuscript will be listed as disclosures at the end of the manuscript. These must be acknowledged in full in the disclosure section of the copyright release and author agreement. Authors without conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject of their manuscript, should acknowledge this on the copyright release and author agreement. Failure to include this information in the manuscript may delay evaluation and review of the manuscript.

C. Authors are expected to provide detailed information about all relevant financial relationships within the past two (2) years as described in GUIDELINES FOR CNS MEMBERS, GUIDELINE 1A1(i-iii). If authors are uncertain about what constitutes a relevant financial interest or relationship, they should contact the editorial office.

D. For all accepted manuscripts, each author's disclosures of conflicts of interest and relevant financial interests and affiliations and declarations of no such interests will be published. The policy requesting disclosure of conflicts of interest applies for all manuscript submissions, including letters to the editor and book reviews. If an author's disclosure of potential conflicts of interest is determined to be inaccurate or incomplete after publication, a correction will be published to rectify the original published disclosure statement.

E. Authors also are required to report detailed information regarding all financial and material support for the research and work, including but not limited to grant support, funding sources, and provision of equipment and supplies, in the Acknowledgment section of the manuscript.

F. If support was received for the study, the corresponding author must state in writing that he/she had full access to all of the data in the study, takes complete

responsibility for the integrity of the data and the accuracy of the data analysis, and had complete freedom and independence in the decision to publish the results of the study.

G. On submission of a manuscript to *Neurosurgery*, CNS Quarterly and Clinical Neurosurgery all authors must complete and sign a copyright release and author agreement including disclosure information and when applicable, include this information in the disclosure section of the manuscript. If no conflict of interest exists, the following statement, “the authors do not report any conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.” If an employee of sponsor was involved in this study (research design, execution, analysis or write-up), his/her participation should be clearly stated by granting authorship or by listing the person and level of participation in the acknowledgement section of the manuscript.

GUIDELINE 2: *Neurosurgery* /CNS Quarterly /Clinical Neurosurgery Editorial Board Members

A. Editorial board and ad-hoc reviewers members must submit a conflict of interest form to the editor-in-chief annually. If an editorial board member/publication editor is presented with a manuscript that presents a potential or perceived conflict of interest with their own personal or industry relationships, they should discuss this with the editorial board chair or editor-in-chief and/or recuse themselves from reviewing the manuscript if appropriate.

GUIDELINE 3: Editor-in-Chief/Associate Editor

A. Each year the editor-in-chief and associate editors must submit a physician-industry conflict of interest disclosure statement which will be kept on file in the CNS headquarters. If the editor-in-chief or the associate editors encounter a manuscript that could present a potential or perceived conflict of interest, they should recuse themselves from evaluating the manuscript and reassign a non-conflicted reviewer to replace them.