

Guidelines on Neurosurgeon-Industry Conflicts of Interest



American
Association of
Neurological
Surgeons

Guidelines on Neurosurgeon-Industry Conflicts of Interest

Purpose

The neurosurgeon's relationship with industry, referred to throughout these guidelines as commercial interest(s), when properly structured, is an appropriate, beneficial and collaborative partnership to improve patient care. Neurosurgeons are necessary collaborators with commercial interests for technical innovation by providing ideas and feedback, conducting research trials, serving on scientific advisory boards and serving as faculty to teach the use of new technology related to neurosurgical practice. Neurosurgeons with innovative ideas to improve patient care rely on commercial interests to bring their creative ideas to practical application in the healthcare market. The collaborative relationship between neurosurgeons and commercial interests must be structured to avoid pitfalls of improper inducements or incentives.

Therefore, the following guidelines are promulgated and in order to clarify the proper relationships between neurosurgeons and commercial interests.

Guidelines

As part of their professional commitment to excellence in patient care, neurosurgeons must maintain specialized knowledge and skills through continuing medical education programs, seminars and professional meetings. These professional functions may be sponsored by medical device manufacturers, pharmaceutical companies and other businesses, which serve an important role supporting continuing medical education (CME) activities and the development of new technologies that contribute to improved patient care. A collaborative effort between neurosurgeons and commercial interests ensures that patients have optimal surgical outcomes through the invention and testing of new technology, research and evaluation of existing technology, as well as continued education of neurosurgeons in applications of technology in surgical care.

Neurosurgeons must be aware of potential conflicts of interest with patient care when pursuing academic or commercial ventures. There may be contractual or other remunerative relationships between physicians and commercial interests, and these relationships have a potential for creating bias. A potential conflict of interest exists whenever professional judgment concerning choices in patient care has a reasonable chance of being influenced by the self-interest of the neurosurgeon.

The self-interest is often financial in nature. Financial relationships are those in which the neurosurgeon benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (i.e., stocks, stock options or other ownership interest excluding diversified mutual funds) or other financial benefits from an ACCME-defined commercial interest. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research) consulting, research or education support, fellowship funding, speaking and teaching, membership on advisory committees or review panels, board membership and other activities from which remuneration is received or expected.

When such conflicts exist, medical or surgical care decisions may be distorted by personal interests. Disclosure of any potential conflict of interest is required in communications to patients, the public and colleagues and resolution of conflicts will occur prior to a CME activity. The primary goal of surgical care must

benefit the patient and must not be compromised by neurosurgeons' personal interests. Neurosurgeons, as with all physicians, have an ethical obligation to present themselves and the services they provide to patients, as well as any potential conflicts of interests, in a clear, understandable and accurate manner.

Those who have payment or contractual relationships with commercial interests are required to disclose them prior to any educational presentation. According to the Accreditation Council for Continuing Medical Education, (ACCME) 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 financial relationship. The ACCME defines a commercial interest as "any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients." In accordance with ACCME Standards for Commercial Support™, all disclosure information must be provided to CME activity participants prior to the beginning of the CME activity. Speakers, authors, committee members or others in the planning process who have the ability to influence and/or control the educational content must disclose their financial relationships and have any conflicts of interest resolved in advance of the activity.

When faced with a potential conflict of interest a neurosurgeon should consult with the appropriate committee in an institutional or professional society to determine whether a conflict of interest exists and how to resolve it.

It is important that deliberate steps be taken to avoid inappropriate influence from commercial interests in organizations, supported educational meetings, research patient and public education initiatives and interactions with patients in order to preclude biased promotion or support of medical devices, procedures or practice recommendations.

These guidelines have been formulated as a guide to the relationship between the specialty, neurosurgeons and the medical commercial interest.

Ethical Guidelines which form the foundation to the guideline on neurosurgeon-industry conflict of interest:

The physician-patient relationship is the central focus of all ethical concerns.

A neurosurgeon shall, while caring for and treating a patient, regard his or her responsibility to the patient as paramount.

A neurosurgeon shall prescribe drugs, devices and other treatments on the basis of medical considerations and patient needs, regardless of any direct or indirect interests in or benefit from commercial interest.

The practice of medicine may present potential conflicts of interest. When a conflict of interest arises, it must be resolved in the best interest of the patient. If the conflict of interest cannot be resolved, the neurosurgeon should notify the patient of his or her intention to withdraw from the relationship.

A neurosurgeon shall, when treating a patient, resolve conflicts of interest in accordance with the best interest of the patient, respecting a patient's autonomy to make healthcare decisions.

When a neurosurgeon has a financial interest (as defined in Appendix A) that is related to any aspect of a patient's evaluation and care, a potential conflict exists which should be disclosed to the patient. It is unethical for a neurosurgeon to receive compensation of any kind from commercial interests in exchange for using a particular device or medication in clinical practice. Reimbursement at fair market value for documented administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable.

A neurosurgeon who has influence in selecting a particular product or service for an entity (organization, institution) shall disclose any relationship with commercial interest to colleagues, the institution and other affected entities.

A neurosurgeon shall enter into consulting agreements with commercial interests only when such arrangements are established in advance and in writing to include evidence of the following:

- Documentation of an actual need for the service;
- Proof that the service was provided;
- Evidence that physician reimbursement for consulting services is consistent with fair market value; and
- Not based on the volume or value of business he or she generates for the corporate industrial entity.

A neurosurgeon shall participate in or consult at only those meetings at which CME is awarded when they are conducted in clinical, educational or conference settings conducive to fair, balanced and accurate exchange of information.

A neurosurgeon shall accept no financial support from commercial interests to attend industry-related social functions without a related educational element.

A neurosurgeon who is attending a CME activity shall accept no financial support from a commercial interest for attendance. Residents and neurosurgeons-in-training may accept a grant from a commercial interest to attend a CME activity if they are selected by their training institution or CME sponsor and the payment is made by the training program or CME sponsor. Bona fide faculty members at a CME activity may accept industry-supported reasonable honoraria, travel expenses, lodging and modest meals provided directly by, or on behalf of, the CME provider. Commercial interests shall have no involvement in the selection of faculty, topics, location or venues for CME events; that is the sole responsibility of the CME provider.

A neurosurgeon, when attending a non-CME educational activity sponsored by a commercial interest, shall accept only tuition, travel and modest hospitality, including meals and receptions; the time and focus of the activity must be for education or training. When appropriate, faculty may receive a reasonable honorarium, which may include reasonable travel expenses.

A neurosurgeon, when attending a non-CME educational activity sponsored by a commercial interest, shall accept no financial support for meals, hospitality, travel or other expenses for his or her guests or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

A neurosurgeon, when reporting on clinical research or experience with a given procedure or device, shall disclose any financial interest in that procedure or device if he or she, or any institution with which he or she is connected, has received anything of value from its inventor or manufacturer.

A neurosurgeon who is the principal investigator shall make his or her best efforts to ensure at the completion of the study that relevant research results are reported truthfully and honestly with no bias or influence from funding sources, regardless of positive or negative finding.

Appendix A

For purposes of these guidelines:

1. “Commercial interest” includes pharmaceutical, biomaterial and device manufacturers.
2. “CME activities” refer to educational activities that meet the Accreditation Council for Continuing Medical Education (ACCME) criteria to award continuing medical education (CME) to physicians.
3. A “conflict of interest” occurs when a neurosurgeon or an immediate family member has, directly or indirectly, a financial interest or positional interest or other relationship with a commercial interest that could be perceived as influencing the neurosurgeon’s obligation to act in the best interest of the patient.

A “financial interest,” “financial arrangement,” “financial inducement” or “financial support” includes, but is not limited to:

- Compensation from employment;
- Paid consultancy, advisory board service, etc.;
- Stock ownership or options;
- Intellectual property rights (patents, copyrights, trademarks, licensing agreements and royalty arrangements);
- Contracted research, general research support and fellowship funding;
- Paid expert testimony;
- Honoraria and speakers’ fees;
- Gifts;
- Travel; and
- Meals and hospitality.

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.

(Statement Approved by the AANS Board of Directors on 03/27/18)

Guidelines on Neurosurgeon- Industry Conflicts of Interest

www.aans.org

5550 Meadowbrook Drive, Rolling Meadows, IL 60008-3852

P 847.378.0500 • F 847.378.0600

Email: info@aans.org