

GUIDELINES ON NEUROSURGEON-INDUSTRY CONFLICTS OF INTEREST

Purpose

The neurosurgeon's relationship with industry, referred to throughout these guidelines as ineligible company(ies), when properly structured, is an appropriate, beneficial, and collaborative partnership to improve patient care. Neurosurgeons are necessary collaborators with ineligible companies 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 ineligible companies to bring their creative ideas to practical application in the healthcare market. The collaborative relationship between neurosurgeons and ineligible companies must be structured to avoid pitfalls of improper inducements or incentives.

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

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 ineligible companies 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 ineligible companies, 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 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 ineligible company. 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 be a benefit to 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 interest, in a clear, understandable, and accurate manner.

Those who have payment or contractual relationships with ineligible companies 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 an ineligible company with which he/she has a financial relationship. The ACCME defines an ineligible company as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. In accordance with ACCME Standards for Integrity and Independence in Accredited Continuing Education, 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 ineligible companies 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 ineligible medical company.

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 ineligible companies.

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 ineligible companies 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 ineligible companies to colleagues, the institution and other affected entities.

A neurosurgeon shall enter into consulting agreements with ineligible companies 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 ineligible companies 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 an ineligible company for attendance. *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. Ineligible companies 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 an ineligible company, 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 an ineligible company, 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. "Ineligible Company" 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 has, directly or indirectly, a financial interest or positional interest or other relationship with an ineligible company 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, fellowship funding
- Paid expert testimony
- Honoraria, speakers' fees
- Gifts
- Travel
- Meals and hospitality

A "positional interest" occurs when a neurosurgeon 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.

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