PRINCIPLES GOVERNING ACADEMY RELATIONSHIPS WITH EXTERNAL SOURCES OF SUPPORT

American Academy of Neurology American Academy of Neurology Institute November 10, 2021

I. Preamble

The authority of the medical profession is derived from the public trust earned by fulfilling its fiduciary responsibility to its patients. As a professional organization, the American Academy of Neurology, along with the American Academy of Neurology Institute (collectively, "Academy"), strives to bolster this trust. It does so, by exemplifying the ideals of neurology and medicine, as manifested through adherence to its mission and core values. To achieve this goal, the Academy depends not only on revenue from its members but, like most non-profit associations, relies on revenue from external sources. Accordingly, external support requisite to the fulfillment of the Academy's mission must be guided by principles that ensure that public trust will not be violated through real or perceived conflicts of interest.

Relevant to this, these principles are based on the belief that a symbiotic relationship with external funding sources provides potential mutual benefit to patients, neurologists, and the Academy, while being consistent with the goals of external funding sources. At the same time, these principles recognize that relationships with external funding sources pose potential conflicts of interest which may threaten the public trust in the Academy and its members, as well as the trust of its members in the Academy. These principles therefore serve to assure and ensure that use of external support will be used by the Academy to fulfill its mission, to support its members in fulfilling their fiduciary to their patients, and by doing so maintain the integrity of the Academy and the public trust.

II. Overview of Principles

A. Any financial relationship with an external source of support may create a potential conflict of interest for the Academy. Conflicts of interest are common, and although some conflicts are unethical, others are not if appropriately recognized and managed as described in the Academy's *Relationships & Conflicts of Interest Policy* and *Code of Professional Conduct*. The appearance of a conflict of interest may be damaging to the public trust in the Academy and its members, as well as to member trust in the Academy, regardless of whether a conflict exists. Recognizing these conflicts, avoiding them when potentially injurious to the Academy, and appropriately managing them when they are aligned with the Academy mission and values is the fundamental purpose of these principles.

Acceptance of external support risks inappropriate conflicts of interest in two particular situations: 1) when external support is from for-profit companies (or not-for-profit entities funded by, or financially beneficial to, for-profit companies); or 2) when disproportionate support originating from limited sources increases the potential for undue influence and Academy dependency.

B. The Academy recognizes that external sources of support can generally be categorized into three areas: 1) industry; 2) non-industry health care enterprises; and 3) other sources, which include, but are not limited to, philanthropic and governmental grant support. In these principles, "industry" is defined as pharmaceutical and medical device manufacturers. "Non-industry health care enterprises" are generally defined as entities involved in and seeking to profit from activities related to the provision of health care other than through the manufacturing of drugs or devices. Non-industry health care enterprises include, but are not limited to, contract research organizations, group purchasing organizations, electronic health record companies, information technology companies, or other commercial entities providing products or

services in health care. Non-profit health care enterprises are only included in this category if they serve to benefit the interests or revenues of associated for-profit entities. These principles apply generally to financial relationships between the Academy as an organization and these categories of external sources of support. In addition, the Academy has identified specific restrictions regarding relationships between certain categories or types of external organizations and those representing the Academy either as employees or in compensated leadership or voluntary service roles, both in this document and other Academy policies as described below.

- **C.** The Academy Boards of Directors, CEO, and the Executive Team are primarily responsible for ensuring organizational compliance with these principles. However, any individual employed by or representing the Academy must be aware of and comply with these principles when developing or reviewing Academy relationships with external sources of support.
- **D.** These principles should be reviewed every two years by the Executive Committee of the Academy Boards of Directors, the Executive Team, and the current chairs of the Ethics Law and Humanities Committee and Industry Relations Subcommittee to ensure their contemporary relevance to the mission, core values, integrity, and reputation of the Academy.

III. General Principles

The Academy's mission statement and core values provide the template for developing and maintaining appropriate relationships with external sources support. Relationships that are not motivated by the Academy's mission and core values, recognizing the primacy of preserving patient trust, can threaten the Academy's integrity and credibility, from the perspective of its members, its staff, the neurologic profession, regulatory agencies and the public.

Although this document pertains explicitly to the Academy and its relationships with external sources of support, many of these principles are implicit to the conduct of Academy members who serve the Academy in various roles. The *Relationships & Conflicts of Interest Policy* applies to individuals serving the Academy in these capacities. All Academy members, even if not serving in any official capacity within the Academy, may adversely influence public opinion regarding the neurologic profession. Their relationship with external sources of funding must be guided by the *Code of Professional Conduct*.

A. Activities supported by external funding and relationships with external sources of support must be aligned with the Academy's mission and values.

The Academy's mission and values must serve as the standard that determines whether beginning and maintaining a proposed relationship with an external source of support is appropriate for the Academy. The Academy must strive to assure and ensure that its integrity and its actual and perceived objectivity is not biased or compromised by external support relationships. The Academy must identify the acceptable boundaries for external relationships and ensure its independence from any influence that conflicts with its mission and values. For example, relationships with producers of products with the potential to harm the public health and without anticipated medical benefit are not appropriate for the Academy. In addition, maintaining a relationship with an external source of support that exhibits behavior counter to the Academy's mission and values is not appropriate for the Academy.

B. The externally supported activity must directly or indirectly benefit public health, patient care, research, or physician practice.

Public education campaigns and programs for Academy members or the public are integral to the Academy's mission and significantly benefit the Academy's constituency. Externally supported programs

that provide financial benefits to the Academy or to its members but are not mission and ultimately patient centric, are not consistent with the Academy's core values, and provide no significant direct or indirect (e.g. clinician education) benefit to the public are not acceptable.

C. External support should be funded from multiple sources without disproportionate influence from a singular source whenever possible.

The Academy should avoid disproportionate support originating from limited sources to prevent the potential for undue influence and Academy dependency. The Academy recognizes that there may be some activities for which the benefits to its mission and constituency are so great, the potential harms so minimal, and the prospects for developing multiple sources of support so unlikely that single-source support may become an acceptable option.

D. The Academy must comply with applicable laws, regulations, and codes of ethics as they apply to external support of Academy activities and programs, and be respectful of analogous laws, regulations and codes of ethics that independently apply to these external sources.

Many Academy activities and programs are affected by laws, regulations, and codes of ethics, including, but not limited to, those governing continuing medical education, political activities, advocacy, and relationships with industry. In addition, many entities that are current or potential sources of external support for Academy activities are similarly governed by laws, regulations, and their own codes of ethics. The Academy, in establishing and implementing its relationships with external sources of support, should respect and comply with the external source's applicable laws, regulations, and codes of ethics unless there are conflicts with these Academy principles. When conflicts arise between the laws, regulations, and codes of ethics affecting the Academy and its external sources of support, the Academy Boards of Directors have final responsibility for approving an acceptable resolution which may entail not proceeding with a proposed externally-supported activity. For its relationships with industry sources of support, the Academy is a signatory to, and should comply with, the Council of Specialty Medical Societies' ("CMSS") Code for Interactions with Companies in addition to compliance with the principles and guidelines contained herein.

E. The Academy must apply the principles of disclosure and transparency for all external support relationships.

Consistent with expectations outlined in the Code of Professional Conduct and the Relationships & Conflicts of Interest Policy for its members, the Academy has a duty to disclose its financial relationships with external sources of support, which it does on the Academy website, in a manner compliant with the CMSS Code.

IV. Special Guidelines

The following guidelines address several special situations concerning Academy development and utilization of external support.

A. The Academy must preserve control of the Academy's name/logo and Academy content included within externally supported projects, publications, and programs produced by, or in collaboration with, the Academy.

If done in accordance with the General Principles described in Section III and subject to applicable Special Guidelines described in Section IV and Section V, the Academy may accept financial support or renumeration from external sources for projects, publications, and programs produced solely by the

Academy or in collaboration with another organization. The Academy must retain control over the placement and use of the Academy name and logo and of any content the Academy creates and contributes to the externally supported project. The Academy must disclose and disclaim endorsement of any content used in an externally supported project that was not created by the Academy or was not reviewed and approved by the Academy.

B. The Academy must not involve itself in the production, sale, endorsement, or marketing to consumers of products that claim a health benefit.

The Academy must not participate in any marketing to consumers of health-related products that claim a health benefit (e.g., pharmaceuticals, medical devices, and home health care products). Educational materials created by the Academy in any format intended to educate the public regarding health care issues must include language, located conspicuously, disclaiming the Academy's endorsement of any company or product advertised in that material.

C. Relationships between the Academy and external sources of support must not permit or encourage influence by the external source of support on Academy policies, priorities, or actions.

An Academy relationship with an external source of support must not permit influence, or the appearance of influence, by the external source of support on Academy policies, principles, priorities, or actions. For example, agreements stipulating access by representatives of the external source of support to Academy leadership would be of concern. Additionally, some relationships that appear to be acceptable when viewed in isolation, may represent an unacceptable precedent when viewed in light of other existing, proposed or potential future Academy priorities and activities.

D. Receipt of support from an external source does not imply Academy's endorsement of the external source of support, its products, services, or policies.

The Academy must not exert any influence to advance the external source's interests outside the substance of the externally supported arrangement itself. The Academy's name and logo should not be used in a manner that would express or imply an Academy endorsement of the external source's products, services, or policies, except within the context of externally supported arrangements that are compliant with these principles.

E. Funds from external funding sources must not be used to support the governance activities of the Academy and Academy leaders must be free of certain relationships with external funding sources during their term of service.

- (1) The Academy must ensure implementation of the Academy's mission, vision, and goals occurs without undue influence by external funding sources. Therefore, organizational support for the activities of the Academy's Boards of Directors, Committees, Subcommittees, Work Groups, Task Forces, Sections, and other related Academy groups, by any external funding source is prohibited. These activities must be funded by internal funding sources. In this context, "internal" funds are considered revenues from dues, meeting and course registrations, publications (including subscriptions and royalties), sales of products and services to members, and member donations.
- (2) The following Academy leaders must have no "Direct Financial Relationships" with industry (i.e., a pharmaceutical or medical device company): a) officers of the AAN and AANI (i.e., President/Chair, Vice President, President Elect, Treasurer, Secretary, Secretary-Treasurer (AANI),

Immediate Past President); b) members of the Academy's Executive Team; and c) Editors-in-Chief of Academy publications.¹

- (3) The following Academy leaders must not be employed (i.e., requires filing of an IRS Form W-2) by industry during their term of service: a) members of the Academy's Boards of Directors, Committees, Subcommittees, Work Groups, Task Forces or related Academy groups; b) chairs or vice chairs of Academy Sections; and c) trainees, trainers, or mentors in Academy's advocacy skills and leadership training programs.¹
- (4) Rules and disclosure management related to authors and reviewers of clinical practice guidelines, performance measures, and related quality improvement documents are described in the Academy's Clinical Practice Guideline Process Manual and the Quality Measurement Manual.
- (5) The Academy's *Relationships & Conflicts of Interest Policy* governs individuals serving the Academy in many capacities including the above and other roles (e.g., faculty members, authors, appointees to outside organizations, authors of Academy position statements, etc.) to ensure these individuals exercise impartial judgments for the best interests of the Academy, AAN members, and their patients. The Academy collects and reviews disclosed relationships with industry, contract research organizations, group purchasing organizations, and other types of external organizations. Review occurs before appointment and throughout Academy service. Possible courses of action to address disclosed relationships include disclosure, recusal, or removal from official Academy capacity.
- (6) For purposes of this section a "Direct Financial Relationship" is a relationship held by an individual that results in wages, consulting fees, honoraria, or other compensation (in cash, in stock or stock options, or in kind), whether paid to the individual or to another entity at the direction of the individual, for the individual's services or expertise. The term Direct Financial Relationship does not mean: a) stock ownership or intellectual property licensing arrangements; b) reasonable compensation for serving on an independent data safety monitoring board in an industry study; c) research support if the research grant is paid to the institution (e.g., academic medical center) or practice where the research is conducted, and not to the individual. (See Principle 1.4 of the CMSS Code for Interactions with Companies and its annotation for additional clarification of Direct Financial Relationship and what relationships are allowable.)

F. Funds from external funding sources must not be used to support Academy advocacy activities.

The Academy acknowledges that its integrity and effectiveness in fulfilling its mission through advocacy would be compromised by allowing its advocacy efforts to be influenced by external funding sources. To ensure its independence, all Academy direct lobbying and formal political advocacy activities, such as Neurology on the Hill, must funded solely from internal revenue sources. Advocacy skills programs, such as the Palatucci Advocacy Leadership Forum, may be supported by external funding if done in accordance with Section V.G.

G. External funding sources must not influence content appearing in Academy publications.

The credibility of Academy sponsored publications and the trust of those that rely on them is dependent on insulating their content from conflict of interest concerns imposed by external funding. Except for

¹ The Academy will permit leaders in the above roles who are elected or appointed prior to the date the Boards of Directors approved these amendments to the principles (August 20, 2020) to maintain existing relationships until April 24, 2021. Until this date, these relationships must be disclosed and managed in accordance with the *Relationships & Conflicts of Interest Policy*.

industry-sponsored supplements (as described in Section V.E.), external funding sources must have no authority in choice of authors for these publications, no opportunity to directly affect content, or be provided access to any individual responsible for the content of that publication, including editors, authors, or reviewers. Publication of manuscripts identifying research results funded by or favorable to industry is appropriate and consistent with the Academy mission if the source of data and funding is properly disclosed.

V. Special Guidelines Concerning Academy Relationships with Industry

Through effective regulation, the Academy can minimize both conflicts of interest and the appearance of conflicts of interest in its relationship with industry. By doing so, it hopes to promote enhanced member, patient, and public confidence in the Academy's independence, credibility, and integrity. Academy policies governing relationships with industry are configured to allow appropriate areas of mutual benefit while, most importantly, maintaining the Academy's high ethical and professional standards and protecting its most valuable and cherished asset, its credibility and integrity as a professional organization. The Academy recognizes that for certain offerings that are clearly marked as industry marketing opportunities (e.g., exhibit hall, industry therapeutic updates, industry-sponsored supplements) AAN members have the autonomy to decide whether to engage with those offerings or not.

These special guidelines specify how the Academy should address receipt of industry support for specific areas, programs, and offerings, and supplement the General Principles and Special Guidelines stated above.

A. Exhibit Hall.

The Academy: (1) may continue soliciting industry to exhibit and hold presentations within the Academy's exhibit hall; and (2) should continue to enforce Academy policies and guidelines related to exhibitors. An attendee's personal contact information must not be provided to exhibitors unless voluntarily provided by the attendee to the exhibitor (e.g., by allowing the exhibitor to scan their badge).

B. General Sponsorship at Academy Conferences, Events and Programs.

The Academy should: (1) increase efforts to pool diversified sponsorship from industry and other sources of support into a single general fund to support Academy meeting and conferences, events and programs; (2) ensure that the magnitude of any single source of revenue within pooled sponsorship does not have disproportionate influence on the content of individual conferences, events and programs; and (3) not accept industry funding for non-educational events without direct or indirect benefit to patient care or fulfillment of the Academy's mission at Academy conferences.

C. Industry Therapeutic Updates.

The Academy may continue non-CME Industry Therapeutic Updates in accordance with Academy guidelines related to industry participants, but (1) may deny any company the opportunity to host an Industry Therapeutic Update if the company is exhibiting conduct that conflicts with the Academy's mission and values and (2) should consider expanding the option of hosting updates to non-industry health care enterprises, as described in Section II. B.

D. Industry-sponsored Neurology® Supplements.

The Academy may continue the practice of publishing Neurology® industry-sponsored supplements, but it should; (1) increase disclosure by more conspicuously placing disclosure language in each industry-sponsored supplement; and (2) increase editorial oversight of industry-sponsored supplements.

E. Academy Developed Quality Improvement Documents.

The Academy develops clinical practice guidelines, performance measures, other quality improvement documents and derivatives of such documents (collectively, "Quality Documents"). The Academy must: (1) not accept industry funds to develop Quality Documents; (2) not permit direct industry support for the initial printing, publication, and distribution of Quality Documents; (3) prohibit industry logos, product logos and promotional information on Quality Documents (including reprints); and (4) prohibit authors of Quality Documents from speaking about the Quality Document they authored or serving as an expert witness about the Quality Document, on behalf of a company in industry, if that company could be positively or negatively affected by care provided in adherence with the Quality Document, for a period of one year after the Academy's publication of the Quality Document.

The Academy may permit: (1) after initial development, printing, publication and distribution is complete, the acceptance of industry support for distribution of Quality Documents through industry purchase of reprints of Quality Documents; and (2) with Academy approval, the appropriate placement of industry name and, as needed to comply with applicable FDA guidance, other required information on or attached to any Quality Documents that includes an off-label use. The Academy requires a written statement to be conspicuously placed on reprints of Quality Documents purchased by industry acknowledging that the content of the Quality Documents was developed solely by the Academy, independent of industry influence.

F. Advocacy Skills and Leadership Training Programs.

The Academy: (1) may seek external funding for advocacy skills and leadership training programs; (2) should seek diversified sources of support, without disproportionate influence from a single source; (3) must organize training and develop content for programming that is independent of influence from the external source of support; (4) will provide advanced notice of the external funder's presence at the program; (5) will obtain participants' permission in advance of sharing participants' personal contact information with the external funder; and (6) external funding must not be used for expenses directly related to the participants, but instead may be used for staff, non-physician faculty, and other related expenses.

G. Industry Roundtable.

The Academy may continue the Industry Roundtable, but (1) may deny membership or remove from membership any company exhibiting conduct that conflicts with the Academy's mission and values and (2) should consider expanding the Industry Roundtable membership model to include non-industry health care enterprises, as described in Section II. B.

VI. Special Guidelines Concerning Continuing Medical Education ("CME")

The Academy complies with the Accreditation Council for Continuing Medical Education's *Standards* for *Integrity and Independence in Accredited Continuing Education* and the principles concerning CME programming in the Council of Specialty Medical Societies' *Code for Interactions with Companies*. In addition, the below guidelines apply to Academy CME programming.

This section applies to relationships with any "Commercial Interest²" in relation to Academy CME programming. A "Commercial Interest" is any entity producing, marketing, selling, re-selling, or distributing health care goods or services consumed by, or used on, patients, or is otherwise involved in and seeking to profit from activities related to the provision of health care. Commercial Interests include pharmaceutical, medical device, and scientific product companies, manufacturers of health-related wearable products, group purchasing organizations, pharmacy benefit managers, contract research organizations, electronic health record companies, health care technology companies, insurers, and advertising, marketing, or communication firms whose clients are commercial interests. Commercial Interests do not include organizations that provide clinical services directly to patients or organizations whose primary mission is to educate health care professionals (e.g., academic medical centers).

This section applies equitably to all Academy sponsored CME activities, regardless of the location of that activity or the language in which Academy sponsored materials are provided.

A. The Academy requires a written statement to be conspicuously placed on all signage related to Academy sponsored CME programming and products when supported by a Commercial Interest(s) that states: (1) the name of the Commercial Interest (company or product logos are prohibited); (2) that the funding was made through an educational grant to the Academy; (3) that the Academy was solely responsible, with no influence from the Commercial Interest, for selection of content, format, presenters, and moderators of the CME program; and (4) that the speakers or authors have not been contacted or influenced in any way by the Commercial Interest with regard to the CME program.

- B. All Academy sponsored educational program speakers must prepare an introductory slide that: 1) identifies both relationship disclosures (whether relevant or not to their presentation) and any conflict of interests (relevant to their presentation) they may have; and 2) remains on the screen for a minimum of 20 seconds (unless no relationships exist).
- C. All speakers at Academy sponsored educational programs must utilize generic names for any pharmaceutical agent discussed in their presentation.
- D. Academy members having access to Academy branded resources (e.g., power point templates) must not utilize those resources in any non-Academy sponsored activity without Academy permission. Additionally, Academy members having access to Commercial Interest-branded resources (e.g., slide decks produced by a Commercial Interest for the purposes of marketing or dissemination of results) must not utilize those resources in any Academy sponsored activity without Academy permission.

Policy history: Approved on June, 26, 2004, by the AAN Board of Directors (AAN Policy 2004-16). Amended on June 12, 2010, by the AAN Board of Directors (AAN Policy 2010-24) and the AANPA Board of Directors (AANPA Policy 2010-16). Amended on August 1, 2011, by the AAN Board of Directors (AAN Policy 2011-21). The Office of General Counsel edited this policy to reflect the dissolution of AAN Enterprises, Inc. effective December 31, 2012. Amended on August 20, 2020, by the AAN and AANI Board of Directors.

² "Commercial Interests" encompass the Accreditation Council for Continuing Medical Education's definition of "ineligible companies" from the *Standards for Integrity and Independence in Accredited Continuing Education*