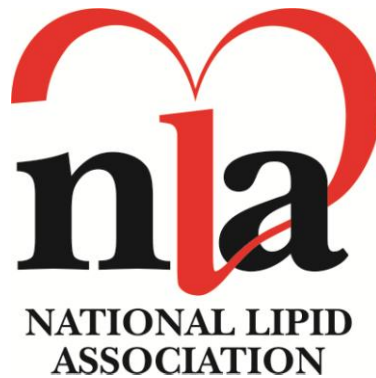


# **National Lipid Association**

## **Code For Interactions with Companies**



**Adopted November 13, 2010**  
Technical Edits March 22, 2011

**This policy has been adopted from:**

- 1) The existing NLA Industry Policies**
- 2) The current CMSS Guidelines for Interactions with Companies**

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## **I. INTRODUCTION**

The National Lipid Association (“NLA”) plays an important role in reaching out to healthcare professionals, patients, and other groups. Our members guide research, discover new therapies, and engage in high quality medical practice.

The NLA offers educational opportunities that help translate scientific and medical progress into the efficient delivery of effective medical care, develops resources that guide our members in advancing medical care, and provides a forum for presenting new skills and scientific developments.

Members and patients count on the NLA to be authoritative, independent voices in the world of science and medicine. Public confidence in our objectivity is critical to carrying out our mission. We know the public relies on us to minimize actual and perceived conflicts of interest.

The NLA is taking the necessary steps to ensure that all relationships and interactions with Companies meet high ethical standards. These interactions with Companies may include receiving charitable contributions, applying for grants in support of programs and activities, and conducting a range of business transactions. Throughout all interactions, the NLA is committed to acting with integrity and transparency.

The NLA adopts this Code for Interactions with Companies (“Code”) to reinforce the core principles that help us maintain actual and perceived independence. Adopting this Code helps to ensure that the NLA’s interactions with Companies will be for the benefit of patients and members and for the improvement of care in our respective specialty field.

## **II. ABOUT THE CODE**

The NLA is a nonprofit, multidisciplinary medical association focused on enhancing the practice of lipid management in clinical medicine representing more nearly 3,000 members worldwide and provides continuing medical education for physicians and other healthcare professionals to advance their professional development and attain certification in clinical lipidology.

In the fall of 2009, at the request of the Board of Directors of the National Lipid Association, the staff of Compass Management was tasked with developing and recommending a voluntary “Code of Conduct” for its Board of Directors, Officers, and Committee Members to enhance professionalism and to disclose, manage, and resolve relationships with industry.

The purpose of this Code is to guide the NLA in the development of policies and procedures that safeguard the independence of its programs, policies, and advocacy positions.

This Code was developed out of the current guidelines developed by the Council of Medical Specialty Societies. This Code will be recommended for adoption at the November 2010 Board of Directors meeting for the NLA.

### III. DEFINITIONS

*The following terms are defined for purposes of this Code. The NLA recognizes that some of these terms may be used or defined differently by individual societies or outside groups. Some of these terms refer to types of interactions in which the NLA may engage with non-profit organizations and individuals as well as with Companies.*

**Association CME/CE:** Programs that are planned by the NLA and for which the NLA, as an accredited CME/CE provider, provides credit

**Board of Directors:** The Board of Directors of the NLA.

**Business Transaction:** An interaction between the NLA and a Company in which the Company pays a fee to the NLA in exchange for the NLA's item, service, or product. Examples of Business Transactions include Company payment of fees associated with subscriptions to NLA publications, advertising in NLA publications, registrations for NLA meetings, and exhibit space rental.

**Chapter Boards:** The Board of Directors of the respective regional chapters of the NLA (The Midwest Lipid Association, The Northeast Lipid Association, The Pacific Lipid Association, The Southeast Lipid Association, and The Southwest Lipid Association).

**Charitable Contribution:** A gift, including an in-kind gift, given by a Company to a qualified 501(c)(3) tax-exempt organization (e.g., the NLA or the Foundation of the National Lipid Association) for use in furthering the organization's charitable purposes and in accordance with applicable tax rules and legal standards.

**Commercial Support:** Funds received by the NLA to support of a CME Activity.

**Company:** A for-profit entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions.<sup>1</sup> This definition is not intended to include non-profit entities, entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients. However, the NLA may choose to adopt a broader definition of "Company" if doing so would better address the NLA's interactions. Examples of a Company include, but are not limited to, insurance companies, medical supply companies, pharmaceutical companies, for-profit healthcare facilities and medical education companies.

**Continuing Medical Education (CME):** Educational activities for which the attendee may receive CME credit (American Medical Association (AMA) Physician's Recognition Award

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<sup>1</sup> See Advanced Medical Technology Association (AdvaMed): Code of ethics on interactions with health care professionals. <http://www.advamed.org/MemberPortal/About/code/>. Accessed May 4, 2009; Accreditation Council for Continuing Medical Education (ACCME): Definition of commercial interest. [http://www.accme.org/index.cfm/fa/Policy.policy/Policy\\_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm](http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm). Accessed December 17, 2009.

Credit, American Academy of Family Physicians (AAFP) Prescribed or Elective Credit, American Osteopathic Association (AOA) Credit— various categories) based on accreditation awarded to the provider by a recognized accrediting body (e.g., Accreditation Council for Continuing Medical Education (ACCME), AOA, AAFP). CME activities “serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession.”<sup>2</sup> For purposes of this Code, educational activities for physicians that are not CME-accredited are considered Non-CME Educational/Informational Programs.

**Corporate Sponsor:** A Company that provides a Corporate Sponsorship.

**Corporate Sponsorship:** An arrangement in which a Company, typically through its marketing department, provides monetary or in-kind support for a particular NLA product, service, or event, and is then acknowledged in connection with the product, service or event. Corporate Sponsorships are distinct from Educational Grants, and do not constitute Commercial Support of CME.

**Direct Financial Relationship:** A compensated relationship held by an individual that should generate an IRS Form W-2, 1099, or equivalent income report.

**Educational Grant:** A sum awarded by a Company, typically through its grants office, for the specific purpose of supporting an educational or scientific activity offered by the NLA. Educational Grants awarded by a Company to support a CME activity are referred to in the ACCME Standards for Commercial Support as “Commercial Support” of CME.<sup>3</sup> An Educational Grant may also be “in-kind” as long as such support does not inhibit, reduce, or seek to control the goals, directions, or outcomes of the activity.

**Key Association Leaders:** Key Association Leaders are officers in the Presidential line of succession (e.g., the President-Elect, the President, and the Immediate Past President), the Secretary, the Treasurer, the Executive Director of the NLA, and the Editor(s)-in-Chief of the NLA Journal.

**Non-CME Informational/Educational Program:** Corporate or direct support of an educational program which the supporter provides educational or promotional information and does not offer CME credit.

**Research Grant:** A sum awarded by a Company, typically through its grants office, for the specific purpose of supporting a research activity.

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<sup>2</sup> Accreditation Council for Continuing Medical Education (ACCME): CME content. [http://www.accme.org/index.cfm/fa/Policy.policy/Policy\\_id/16f1c694-d03b-4241-bd1a-44b2d072dc5e.cfm](http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/16f1c694-d03b-4241-bd1a-44b2d072dc5e.cfm). Accessed October 25, 2009; American Medical Association (AMA): The Physician Recognition Award and credit system. <http://www.ama-assn.org/ama1/pub/upload/mm/455/pr2006.pdf>. Accessed December 18, 2009.

<sup>3</sup> Accreditation Council for Continuing Medical Education (ACCME): Standards for commercial support. [http://www.accme.org/dir\\_docs/doc\\_upload/68b2902a-fb73-44d1-8725-80a1504e520c\\_uploaddocument.pdf](http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf). Accessed December 17, 2009.

**Restricted Grant:** Grant funding that is restricted by the donor for a designated purpose or specified time restriction.

**Satellite CME Symposium:** A Company-supported CME program held as an adjunct to a NLA meeting where CME credit for the Symposium is provided by a third party CME provider, and for which the NLA receives a fee.

**Unrestricted Grant:** Grant funding that is free from any external restrictions and available for general use.

## **IV. PRINCIPLES FOR INTERACTION**

### **1. Independence**

- 1.1** The NLA shall develop all educational activities, scientific programs, events, products, services, and advocacy positions independent of Company influence, and shall develop and adopt policies and procedures that foster independence.
- 1.2** The NLA shall separate their efforts to seek Commercial Support, Corporate Sponsorships, Charitable Contributions, and support for Research Grants from their programmatic decisions.
- 1.3** The NLA shall use written agreements with Companies for Commercial Support, Corporate Sponsorships, Charitable Contributions, and Business Transactions.

### **2. Transparency**

- 2.1** The NLA shall make their conflict of interest policies and/or forms available to their Members, Companies, and the public upon request.
- 2.2** The NLA shall disclose Company support (at a minimum Commercial Support, Corporate Sponsorships, Charitable Contributions, and Research Grants), making this information available to their Members and the public upon request.
- 2.3** The NLA shall adopt written disclosure policies for Key Association Leaders, members of the Board of Directors, committee members, staff, and others who serve on behalf of the NLA, and shall use the disclosed information to manage conflicts of interest in decision-making. The NLA shall require volunteers to update disclosure information at least annually and when material changes occur.
- 2.4** The NLA shall disclose all financial relationships that Key Association Leaders and members of the Board of Directors have with Companies, making this information available to its Members and the public upon request.

### **3. Accepting Commercial Support and Corporate Sponsorships**

- 3.1** The NLA shall only accept Commercial Support or Corporate Sponsorship of an item or program if the item or program is aligned with the NLA's strategic plan, mission, and annual agenda.
- 3.2** The NLA shall make reasonable efforts to seek funding from multiple Companies when possible.

- 3.3** The NLA shall solicit Commercial Support in a non-competitive environment. All grant requests will have a budget attached or be solicited for input by the NLA in the form of RFP to Industry or other education companies.
- 3.4** The NLA shall make every effort to seek multi-supported funding for its programs to avoid situations of perceived conflicts of interest. However, this is not always possible or practical. The goal of the NLA is to ensure its funding and project objectives are met. If a single commercial supporter wishes to fund an entire proposal, it shall be the final decision of the Board of Directors and/or the appropriate NLA committee to move forward with the proposal based upon meeting the stated mission, timeliness, and ethical guidelines.
- 3.5** NLA grants shall include funds for project development, distribution and costs associated with NLA management, intellectual property, and administrative expenses associated with the project. These expenses shall be detailed as part of the overall program budget.
- 3.6** The NLA shall pursue projects based on the objectives of achieving mission goals. In most cases, it is feasible for the NLA to accept funds to pay for all administrative costs and fees associated with the project. In no event, however, will the receipt of such a grant influence the content of any such project.

#### **4. Control of Accepted Projects**

- 4.1** The NLA shall maintain an arms-length relationship with all Companies, Commercial Supporters, and Corporate Sponsors in order to ensure compliance with the agenda of the NLA. Maintenance of ethical relationships with any entity is paramount to the NLA mission.
- 4.2** Regardless of the funding mechanism, the NLA Board of Directors and/or the appropriate NLA committee shall be involved in the project development and review process and most importantly, have final approval of any project developed through a Company relationship before its production, release or distribution to the public. No project shall be undertaken without the support of the Board of Directors and/or the appropriate NLA committee.
- 4.3** Upon receipt of an Unrestricted Grant, the NLA shall maintain full control over the planning, content, quality, scientific integrity, implementation, and evaluation of the activity, and over the selection of speakers, moderators, authors, or other faculty for the activity. Such control is necessary for the NLA to maintain the integrity of the activity and to avoid misconduct and/or any perception of impropriety with a Commercial Supporter or Company. Grants received by the NLA are presumed to be Unrestricted Grants unless expressly written to the contrary.

**4.4** The NLA shall maintain full control over selection of vendors or production companies furnishing services in conjunction with accepted projects.

## **5. Association Meetings**

### **5.1 Commercial Support and Association CME/CE**

- 5.1.1 The NLA shall comply with ACCME Standards for Commercial Support, which includes adoption of policies and procedures designed to identify and manage conflicts of interest in Company-Supported Association CME programs.
- 5.1.2 The NLA shall retain control over the use of Educational Grants and implement safeguards designed to ensure that educational programs are non-promotional and free from commercial influence and bias.
- 5.1.3 The NLA shall appoint their own planning committees to select the objectives, content, faculty, and format of educational activities in a manner that is consistent with their organizational missions.
- 5.1.4 The NLA shall not solicit supporters' suggestions about program topics, speakers, or content.
- 5.1.5 The NLA shall prohibit presenters from using Company-controlled presentation materials and from using slides with Company logos.
- 5.1.6 The NLA shall require presenters in Association CME programs to give a balanced view of therapeutic options and will encourage presenters to use generic names in place of product trade names.
- 5.1.7 The NLA shall not seek support for product-specific topics.
- 5.1.8 The NLA shall make reasonable efforts to achieve a balanced portfolio of support for each Association CME program.

### **5.2 CME-Accredited Satellite Symposia**

- 5.2.1 The NLA shall require Satellite CME Symposia<sup>4</sup> to undergo an application and selection process.
- 5.2.2 The NLA shall require Satellite CME Symposia to comply with ACCME Standards.
- 5.2.3 The NLA shall ensure that Satellite CME Symposia are clearly distinguished from the NLA CME/CE in association meeting programs and promotional materials.
- 5.2.4 The NLA shall not permit Key Association Leaders to participate in Satellite CME Symposia as faculty members, presenters, chairs, consultants, or in any other role when the symposia is taking place during their annual meeting.

### **5.3 Non-CME Informational/Educational Programs**

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<sup>4</sup> See Definition of Satellite CME Symposium. Based on the definition of Satellite CME Symposium, Section 5.2 of the Code does not apply to programs that are held adjunct to Association meetings but (1) are not Company supported; (2) are not CME accredited; or (3) for which Societies do not receive a fee.

- 5.3.1 The NLA shall require Non-CME Informational/Educational Programs to be clearly distinguished from Association CME/CE.

#### **5.4 Presentation of Commercial Supporter Products/Services**

- 5.4.1 The NLA shall ensure that every activity present discussion of multiple treatment options and shall not be expected to focus on a single product, except when options are so limited as to preclude meaningful discussion on the topic area.
- 5.4.2 The NLA shall not allow the direct sale of any product within an educational activity. Therefore, no direct endorsements or advertisements of a particular product will be made during any educational programming, and the commercial interest will understand the need of NLA to provide a disclaimer in the education programs it offers.
- 5.4.3 The NLA shall determine the acceptability of product promotional material integration (e.g., product brochures or samples) as part of an overall public health education package. The Board of Directors shall evaluate the appropriate level of integration and have final approval of any materials created or included for this purpose.
- 5.4.4 At meetings sponsored by the NLA, promotional marketing efforts, including but not limited to the presentation of visual exhibits or displays, written materials, audio, and samples of products will be allowed only in a setting that clearly identifies this as a commercial area distinct and separate from the CME certified sessions. All relevant companies wishing to present promotional materials will be given equal access to provide such materials in the designated area.

### **6. BOARD OF DIRECTORS, OFFICERS, COMMITTEES, AND STAFF**

- 6.1** The Board of Directors and committee members are required to disclose all industry related interests of a direct or influential relationship. Those who refuse to disclose within one year of appointment are removed from their positions. Planners and faculty members who refuse to disclose are precluded from participating in the activity.
- 6.2** Course and activity planners shall carefully consider and select expert faculty who have no known conflicts of interest relevant to the topic that would preclude them from participating. Note: Employees of a commercial interest related to the content of NLA CME activities are not allowed to participate in NLA or Chapter Boards, educational activities, or as planners, reviewers, or faculty.
- 6.3** Should members of the Board of Directors, committee members, or staff have a conflict of interest which may bias the decision for or against a specific proposal, they shall make this conflict known to the Board of Directors prior to any Board of Directors action. The Board of Directors shall adjudicate any disputes.
- 6.4** Honoraria, as established in the approved Honoraria Policy of the NLA, may be granted for work performed in conjunction with the project. This amount shall be

budgeted as part of the NLA administration grant and follow standard policy of the NLA.

- 6.5** Expenses incurred in conjunction with the project shall be reimbursed. Funds for expense reimbursement shall be part of the administrative grant to the NLA.

## **7. COMMERCIAL SUPPORTER RELATIONSHIPS**

- 7.1** All relationships with commercial supporters shall be conducted in accordance with the FDA Final Guidance on Industry-Supported Scientific and Educational Activities (December 1997), the AMA Principles of Medical Ethics, AMA Opinion 8.061: Gifts to Physicians from Industry, AMA Opinion 9.011: Continuing Medical Education (if accredited), and the PhRMA Code on Interactions with Healthcare Professionals (updated January 2009). A letter of agreement between the grantor and NLA shall be signed detailing the terms of the grant and the project considered.
- 7.2** The commercial supporter shall receive appropriate acknowledgement of support in all materials developed. No condition, outside the agreement, shall be placed on the NLA in recognition of support for the project or activity.
- 7.3** The activity shall be focused on educational content and free from commercial influence or bias. Information presented about commercial products shall be evidence-based, objective and based on scientific methods generally accepted in the medical community. Relationships between activity planners, faculty, authors, reviewers and any relevant commercial interests shall be conspicuously disclosed.
- 7.4** The commercial supporter shall not suggest speakers, moderators, or authors.
- 7.5** The use of any materials or rights to materials owned by the NLA prior to or arising out of such an agreement does not confer upon the commercial supporter the right to use such materials for any purpose not related to the agreement.
- 7.6** Any copyright or publication rights arising from any materials used in connection with any such agreement shall belong to the NLA unless otherwise agreed.