

ASN Policy on Managing Conflicts of Interest

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The federal government, foundations, associations, and the Institute of Medicine (IOM) are examining the relationships between physicians and “commercial interests,” particularly biotechnology, medical device, and pharmaceutical companies (Table 1). Discovering a lack of “systematic information” about conflicts of interest (COI) and commercial bias, IOM recently recommended that the federal government study the effect of such conflicts “on the quality of medical research, education, and practice.”¹

The American Society of Nephrology (ASN) shares IOM’s concern over the lack of data related to COI and agrees that more research is needed. However, even in the absence of concrete information, it is the responsibility of a professional society to try to understand the extent to which COI interface with its missions. Perhaps no single aspect of COI for societies and those who represent them is as visible and subject to scrutiny as continuing medical education (CME).

The longest phase of the educational continuum for physicians, CME is also a critical element of the country’s health care system. “Given the accelerating pace of change in clinical information and technology, continuing education has never been more important,” observed the Josiah Macy, Jr., Foundation.² By providing a preponderance of CME, professional societies such as ASN improve the quality of health care.³

In addition to CME, societies like ASN provide access to new knowledge by publishing peer-reviewed journals, support basic and clinical investigation through research grants, and advocate for the development of national health policies. To support these missions, many societies—including ASN—solicit funding from commercial interests.

Although some have argued that professional societies should begin to eliminate such funding, others have suggested that such a restriction “would marginalize critical roles that industry, and many physicians working in industry, play in critical medical research alliances.”^{3,4} Prohibiting industry support could limit the educational offerings provided by societies newly hampered by budget shortfalls. Completely eradicating any semblance of a conflict—and any individual with a corporate relationship—might diminish the pool of qualified speakers a professional society is able to recruit, thus reducing the quality of CME offered, which is the opposite of what such restrictions are meant to produce.⁴

To assess its mechanisms for managing relationships with commercial interests and to consider new approaches for protecting its members from perceived bias, ASN created a committee on corporate relations in 2008. The ad hoc committee (chaired by John B. Stokes, MD, FASN) was charged with developing policies for governing ASN’s interactions with the biotechnology, medical device, and pharmaceutical industries—or any group with which ASN, its leaders, employees, or other individuals whom the review identified might have COI or bias.

The committee reviewed existing interactions between ASN and commercial interests, evaluated relevant literature, and considered COI policies of similar professional and medical organizations. Through a series of interviews with Society leaders and staff who manage ASN’s educational, publications, and fundraising programs, the committee identified areas where the Society effectively restricted industry influence as well as gaps in ASN’s COI policies.

The committee on corporate relations developed ten recommendations on how to design, monitor, and enforce regulations that improve the Society’s interactions with industry. These recommendations are based on the premise that ASN can develop beneficial partnerships with commercial interests as long as the Society’s leaders, staff, and members appropriately and responsibly manage their relationships with these entities.

The ASN Council unanimously approved all ten of the committee’s recommendations, which relate to industry participation, disclosure, evaluation, standardization, and transparency. The implementation of these policies—including programs that improve transparency and documentation—and past initiatives to separate the development of program content from the Society’s interactions with corporations and their representatives, should assure ASN members that the Society is taking the proper steps to prevent bias in the educational and scientific programs in which it participates. ASN is committed to these recommendations and will work in a timely fashion to modify the Society’s existing processes and databases to implement these proposals.

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Table 1. Recent activity concerning COI and commercial bias

Date	Activity
April 2007	The Senate Committee on Finance report states that independent educational programs are used by the pharmaceutical industry for advertising
August 2007	ACCME modifies definition of a commercial interest as it relates to joint sponsorship
November 2007	AAMC holds a workshop on addressing COI with professional medical associations
December 2007	ACCME clarifies policy on standards for commercial support (SCS)
January 2008	Senator Grassley asks the American Heart Association and the American College of Cardiology for details on industry funding
April 2008	The AAMC Task Force on Industry Funding of Medical Education releases recommendations for managing industry participation in medical education
May 2008	The Josiah Macy, Jr., Foundation publishes conclusions and recommendations from 2007 conference
June 2008	ACCME, Accreditation Council for Pharmacy Education, and American Nurses Credentialing Center respond to Macy Report
June 2008	ACCME publishes report on whether the literature supports evidence of bias in commercially supported CME
June 2008	ACCME issues two "Calls-for-Comment" and informational items on new ACCME policies relative to SCS
June 2008	ACCME provides statement to IOM
June 2008	AMA considers resolution
June 2008	American Association of Medical Society Executives responds to AMA resolution
June 2008	Senate Special Committee on Aging requests information from ACCME
July 2008	Pfizer changes CME funding model
July 2008	Senator Grassley asks the American Psychiatric Association (APA) for details on industry funding
July 2008	PhRMA revises "Code on Interactions with Healthcare Professionals"
July 2008	ACCME initiates "formal inquiry" of several medical societies, including ASN
March 2009	APA votes to eliminate industry-sponsored symposia and meals
April 2009	<i>Journal of the American Medical Association (JAMA)</i> authors propose recommendations for professional medical associations' interactions with industry
April 2009	The Independent Drug Education and Outreach Act (S 767/HR 1859) is introduced in Congress
April 2009	ACCME issues calls for comment regarding CME designations and funding
May 2009	IOM releases report on "Conflict of Interest in Medical Research, Education, and Practice"

INDUSTRY PARTICIPATION

Legislators, policy-makers, patients, and physicians have reasonable concerns about the influence of commercial interests over CME. As cited in numerous reports, industry-funded CME has the potential to influence clinical decision-making.^{3,5} However, the mere presence of commercial interests does not indicate influence. Rather, certain behaviors—such as corporate involvement in speaker selection—are associated with potential bias.

To insulate the Society, ASN has created a firewall that limits all engagement between industry representatives and education planners. The firewall effectively—yet not onerously—protects the integrity of CME and ensures that industry support enhances, but never dictates, the programs ASN provides for its members.

Recommendation 1

Only personnel not involved in planning or implementing educational content or ASN public policy should conduct fundraising activities for the Society. From time to time, it is in the best interests of ASN to participate with corporate sponsors in the areas of health policy, research, and program development, to name a few. Thus while fundraising activities should be separate from program development, the Society should not avoid interactions with corporations that serve to advance the missions of the Society.

A firewall allows ASN leaders to create educational programs without considering which company will sponsor its costs, avoiding the danger of considering how program decisions might encourage greater company funding. The Society is opposed to eliminating industry support completely because it would likely diminish the quality and quantity of CME, in turn reducing physicians' knowledge of new technologies and practices and impacting overall patient care.

Recommendation 2

ASN should maintain its policy of prohibiting corporate influence in the planning of its educational symposia, which are accredited by the Accreditation Council for Continuing Medical Education (ACCME). The specific planning and identification of speakers for all symposia should be the sole responsibility of the relevant planning committee. ASN should not accept planned programs proposed by educational companies on behalf of corporations.

The Society recognizes the hidden influence industry has through medical education and communication companies (MECCs). As reported by the Senate Finance Committee in April 2007, "the use of third-party CME providers makes it difficult to demonstrate that the educational programs' favorable product messages should be attributed to the sponsoring drug company."⁶

In response to the finance committee's concerns, ASN es-

established strict rules for MECC collaboration on industry-sponsored symposia that prohibit any engagement with industry before contact and programmatic discussion with the Society. ASN intends to track its involvement with MECCs to ensure its policies are effective, but believes an outright ban on their involvement may be against the Society's best interest because MECCs can be "innovative, they're efficient, and they have competencies that other provider groups often lack."⁷

Although some groups have called for professional medical associations to stop "endorsing...industry's programs, facilitating their operation, or profiting from them," ASN has found that the quality and effectiveness of associated symposia have improved drastically since the Society became involved.³ Rather than returning to a model in which the quality of these programs is in question, ASN plans the programs with heightened scrutiny.

DISCLOSURE

In considering its policies, ASN had to differentiate between organizational relationships and its members' individual relationships with commercial interests. By virtue of nephrology's expansiveness, many members have numerous opportunities to collaborate with, and benefit from, industry. These opportunities include participating in trials, sitting on boards, and speaking on a company's behalf. Recognizing this fact, ASN requires its leaders, members, and speakers to disclose all information related to financial and professional conflicts; yet the Society is unwilling to prevent qualified nephrologists from participating in its activities solely because a relationship is cited.

To maintain and benefit from the involvement of these leaders, the Society supports processes that effectively review, document, track, and respond to concerns about potential conflicts.

Recommendation 3

The Society should rename the present disclosure form as "the Financial Disclosure and Potential Conflict of Interest Form." The revised form should include disclosure of two kinds of information: (1) activities related to other societies with similar missions and (2) financial interests related to private corporations (including royalties):

- *The Financial Disclosure and Potential Conflict of Interest Form should include a level of financial involvement with private corporations.*
- *ASN should develop a process for reviewing the Financial Disclosure and Potential Conflict of Interest Form and taking action in cases where further information is needed or where a potential conflict exceeds a threshold.*
- *The Society should educate its group leaders about their responsibility to review the revised Financial Disclosure and Potential Conflict of Interest Form, and discuss with their groups the need for additional information specific for each group's activity. Furthermore, the information included on these forms should be considered confidential.*

ASN leaders and staff must collaborate to manage the formalized review, whereas the Society believes a second-level of review is necessary to adjudicate any conflicts as well as ensure consistency and fairness. The guiding principles articulated by the Federation of American Societies for Experimental Biology for its researchers extend to all aspects of medicine: Individuals "must operate with transparency... [and] must be accountable to stakeholders."⁸ ASN's leaders will identify when conflicts require further action and will either prohibit those individuals from participating in Society activities or require them to disqualify themselves from pertinent discussions.

ASN typically requires those members participating in a committee or in one of the Society's educational programs to complete a disclosure form. However, the Society now feels that disclosure should be required of all individuals involved in any activity promoted or supported by the Society.

Recommendation 4

Individuals who review manuscripts submitted to the Society's journals should complete an annual COI disclosure form that can be updated. ASN will develop software to integrate submission and review of manuscript reviewer disclosures into the peer review process. The relevant editor or associate editor should review the forms for any potential COI. Identified potential conflicts should be subject to action by the editor or associate editor. Actions taken by the editor should be recorded in the journal's review documentation.

Recommendation 5

The ASN Program Committee (which helps plan the Society's annual meeting) should review the process of disclosure required for abstract reviewers. Specifically, the primary reviewers should avoid grading an abstract if (1) there is a potential conflict with an institutional affiliation with an author (as currently exists) or (2) if the reviewer has a financial involvement with a product or the competitor of a product mentioned in the abstract. Program committee members should excuse themselves from voting on a presentation if they have a financial involvement with a product, or competing product, mentioned in the abstract.

ASN believes that professional societies must offer additional consideration to the role of review on the dissemination of scientific knowledge. Undeclared corporate bias in one reviewer may greatly influence the acceptance of a manuscript or abstract, which may then influence clinical opinion and practice. In terms of abstract review, the Society is especially conscious of the financial implications associated with presentation. There are many examples in which an individual company's stock value fluctuated based on the presentation of the results of a clinical trial. Any attempt to improve disclosure must start at the beginning of the educational process and must include all participating individuals.

In terms of speaker disclosure, ASN believes current provisions fail to truly inform the participant of what conflicts may exist. For example, the Society maintains that it is vital for the moderators of educational sessions to highlight the potential conflicts for each speaker in that session.

Table 2. Organizational recommendations for addressing concerns about COI

Issue	JAMA Authors	IOM
Limits industry support for Society programming	Imposes a complete ban on pharmaceutical and medical device funding except for advertising and exhibit fees. Until change can be made, restricts total industry funding to 25% of operating budget. Those funds should be pooled and distributed through a central repository.	Proposes a new system of funding CME via a consensus development process. Options include maintaining indirect industry funding, implementing a central entity for distributing funds, and restricting industry support (but identifying new funds for CME).
Manages Society control of educational content	Establishes an institutional/organizational CME committee responsible for distributing educational grants. Members should be conflict-free and have control over topic and speaker selection. Prohibits identification of industry support for specific lectures/individuals.	Concludes that the current system of funding CME is unacceptable, but does not offer specific rules for changing the process.
Sets requirements for COI disclosure of program committee members	Requires, at a minimum, members of program committees to disclose any financial ties with industry. Recommends making disclosures publicly available.	Requires financial disclosure on an annual basis and when significant changes arise. Disclosures should be significantly specific, without a minimum monetary threshold. Institutions/organizations should make the process as administratively simple as possible for respondents and require further disclosure when necessary.
Determines appropriate distribution of industry-specific material	Prohibits distribution of corporate-branded items to members. Prohibits the appearance of company logos on tote bags, lanyards, etc. Requires standards of conduct in the exhibit hall, including a ban on gifts and food.	Prohibits the acceptance of items of material value from industry, at campus and off-campus settings. Encourages professional associations to adopt supportive policies.
Dictates Society involvement in industry-sponsored symposia	Restricts completely collaborating in, or profiting from, industry marketing activities. Prohibits association endorsement or facilitation of industry programs.	NA
Prevents industry influence over Society journals	Prevents association publications from bearing the logo of a drug or device company. Disallows industry funding for journal supplements.	NA
Encourages policies that prevent industry influence via journal advertising	Requires association journals to institute advertising policies that protect editorial decision-making from the effect of advertising interest.	NA
Requires appropriate disclosure or conflict-free status for Society leaders	Requires officers and board members, but at a minimum officers, to be conflict-free (\$0 threshold, no personal income or research support from industry) at the time of election through their period of service.	Requires the implementation of financial COI policies for all individuals whose decisions impact the organization's mission. In practice, these policies will also pertain to relevant, nonfinancial relationships, such as leadership positions. Encourages creation of national guidelines and procedures for disclosure.
Establishes a process for reviewing COI	Requires a formal mechanism for reviewing disclosure. Encourages some combination of president, chief executive officer, general counsel, and compliance officer to lead review. Requires detailed and explicit disclosure with sections for activity description and sums received.	Encourages the formation of a standing committee with members free of conflict and with relevant expertise. The committee should use a full range of management tools, including eliminating the conflicts, removing individuals from the relevant activity, and requiring additional disclosure.

Although each group commented on other issues—JAMA authors on affiliated foundations, IOM on National Institutes of Health research, AAMC on prescription drug samples, etc.—the chart topics are the issues that impact society interactions with industry, as agreed upon by most groups. NA, not applicable.

Table 2. Continued

AAMC	ASN
Encourages national medical organizations to define processes to ensure objective CME. Does not restrict industry funding.	Maintains relationships with industry as long as there is a clear firewall between the development of program content and the Society's interactions with corporations.
Establishes a central CME office to distribute funds. Encourages a cooperative academic medicine-industry effort to develop information systems for CME. Requires recognition of industry funding sources for all CME activities.	Charges the Society's educational committees with controlling all educational content and maintains a strict firewall between fundraising and educational development. Continues to identify industry support for meeting sessions and materials.
NA	Requires members of the program committee (and all Society committees and advisory groups) to thoroughly disclose their financial and professional relationships. Maintains that disclosures should be reviewed by the staff and leadership, but otherwise remain confidential.
Prohibits the acceptance of gifts from industry by physicians and other faculty, staff, students, and trainees, whether on-site or off-site.	Prohibits speakers from participating in exhibit hall presentations and/or activities. Allows the distribution of branded items on the basis of PhRMA guidelines.
Requires academically oriented management of CME programs and prevents industry from restricting the content of programs it sponsors or specifying which faculty or other persons should be selected as presenters.	Prohibits corporate influence in the planning of educational symposia. The specific planning and identification of speakers must remain the sole responsibility of the relevant planning committee.
NA	Encourages analysis and possible reconsideration of the process for accepting journal supplements.
NA	Does not comment on this issue because the Society's journals already abide by rules protecting editorial decision-making.
NA	Requires financial and professional disclosure of leaders, chairs, and committee members.
Requires institutions to develop audit mechanisms to ensure ACCME compliance.	Institutes a two-level review process to assess conflicts and ensure consistency. Establishes a COI committee to adjudicate concerns about conflict and continually assess the Society's programs and policies to prevent industry influence.

Recommendation 6

ASN should require its moderators to clearly and completely declare the speakers' relationships (financial and other) at the beginning of sessions. While ACCME regulations require speakers to disclose all financial interests, the moderator is responsible for highlighting specific information about financial ties to organizations that make products that are relevant to the subject discussed in the session. The Society should consider creating a threshold value necessary for declaring "significant" financial involvement. The ASN Education Committee should develop a system for evaluating the extent to which speakers comply with the instituted policies.

ASN, like many other professional societies, represents a broad membership of physicians and investigators with varying degrees of understanding about the products created by commercial interests, such as industry. Therefore, ASN believes meeting participants should learn how disclosed relationships relate in the context of the speakers' discussions.

By charging the moderator with improving disclosure, the Society is encouraging greater moderator involvement in preventing, tracking, and responding to bias. New requirements could include increasing moderator participation in premeeting presentation review, educating moderators on how to manage bias arising during a presentation or question and answer period, and restricting moderators from serving as presenters during the session in which they are moderating. Clear policies that inform and direct moderators on responding to bias concerns will enhance the Society's ability to provide high-quality, bias-free CME in the future.

In addition, mechanisms to support documentation—such as a centralized database—will allow ASN to track potential conflicts and document any transgressions among its speakers, reviewers, and leaders. Such a system will allow the Society to better understand individuals' financial and professional backgrounds before they are invited to serve.

To further protect the integrity of CME, ASN agrees with previous reports that marketing and educational activities must remain completely distinct, with no opportunity for overlap (even if such crossover is coincidental rather than manipulative). As such, the Society believes that a second firewall should be built between advertisers and educators.

Recommendation 7

ASN should prohibit individuals involved in corporate-sponsored exhibits or marketing activities from participating in educational activities (such as CME) during ASN Renal Week (the Society's annual meeting) and vice versa.

EVALUATION

Although encouraging the implementation of numerous processes to prevent bias, ASN maintains that the best mechanism for protecting educational programming in the long term is to

require broad evaluation. To date, the Society is disappointed by the response rate for meeting surveys and the quality of these instruments.

Recommendation 8

ASN should institute a more thorough process for evaluating the appearance of commercial bias in educational presentations.

- The Society should require "educated" reviewers to monitor all major presentations at its educational meetings. ASN believes that the session moderators are the most logical people for this task. The meeting planners should provide reviewers with appropriate instructions on how to identify commercial bias. They should also assess evaluations from the assigned reviewers.
- The Society should require participants who complete evaluation forms to be specific about why they detected commercial bias in a meeting or presentation. Asking participants if they detected bias or commercial bias will require education of the audience.

Currently, participants seeking CME credits respond to the question of whether they "perceive[d] commercial bias; defined as the obvious appearance of skewed material which has been influenced by commercial support."⁹ Yet responses appear random at best, and anecdotal evidence suggests that the mere presence of industry—whether in the exhibit hall or recognized on signage—leads to responses of perceived bias.

To collect accurate data, ASN must question a broader selection of meeting participants, educate respondents on what constitutes bias in the educational arena, and require participants to thoroughly explain where they perceive bias. Once the Society properly understands where there are concerns—and where perceived corporate influence is not actually impactful—it will create a system to evaluate and address issues of bias after its educational meetings.

STANDARDIZATION AND TRANSPARENCY

Long-term evaluation will require continual review and update to ASN's policies related to COI and bias. This effort will require a substantial, but necessary, investment in ASN's infrastructure.

Recommendation 9

ASN should develop a group or committee to review the Society's COI activities and policies as well as its instituted documentation processes.

Such a committee is essential to review current policies and practices on an annual basis and recommend changes accordingly. Recommendations might be based on changing national standards and ideas or operational and practical matters within ASN. This committee can also serve as the second level of review of perceived COI and bias and as an arbiter for actions taken in response to conflicts or allegations; serve as a

core cog in the Society's machinery for standardizing and communicating policies to its membership and the Society's corporate partners; and help ensure that everyone associated with ASN (including the Society's staff) continue to understand the rules in a fluid, ever-changing environment.

Recommendation 10

ASN should develop clear guidelines for informing the Society's representatives (members and staff) and commercial interests of its expectations and policies. Selected ASN staff should be expected to know (or have access to) the policies of ASN, IOM, the Association of American Medical Colleges (AAMC), the Pharmaceutical Research and Manufacturers of America (PhRMA), the American Medical Association (AMA), and ACCME. In addition, ASN should begin a process to communicate to its members the steps being taken to ensure objectivity in its programs and policies. The Society might consider developing an electronic forum where members can raise questions and concerns about the relationship of ASN's programs with commercial interests.

In an era of increased scrutiny of industry partnerships, myriad organizations are offering recommendations for how best to manage potential conflicts. ASN leaders must be aware of requirements that affect the implementation of educational programming and consider the ways in which national guidelines—put forth by the medical community rather than dictated by external entities—could improve the provision of the Society's services.

ASN considered various options for interacting with commercial interests and purposely chose to direct its attention to managing its relationships with these entities.¹⁰ Some of the Society's policies closely follow the recommendations of other organizations (such as IOM), whereas others rest on the other side of the spectrum (such as AAMC). However, regardless of the ultimate decision made on resolving COI and bias, all parties appear to agree on the broad issues that require attention (Table 2).

ASN's policies are strict to the extent that the Society is intolerant of corporate influence on its activities. However, ASN recognizes and appreciates that industry support is vital to the Society's ability to provide its members with the premier tools and opportunities necessary to be successful in an ever-expanding medical field.

The management of COI is a long-term process, and ASN encourages ongoing discussion, input, and guidance from the Society's members on how best to interact with commercial interests. ASN is acutely aware that concerns about conflicts and bias are leading federal and state governments to intervene in what has always been a self-regulating profession.

Although individual actions are necessary first steps in the process, ASN calls on other professional societies to join together to articulate national standards for managing relationships with commercial interests. There are many interpretations of "ethical guidance" for interacting with commercial interests, and if physicians do not articulate their own standard, a disparate one will likely be forced upon them.¹¹

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Committee and Council

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DISCLOSURES

None.

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See related editorial, "Managing Conflicts of Interest: The Road Ahead," on pages 1860–1862.