

Managing Conflicts of Interest: The Road Ahead

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Recent allegations have accused “respected experts” for purportedly promulgating information and opinions to physician-consumers while concealing their conflicts of interest (COIs) and commercial bias.¹ The news blitz stemming from these transgressions has led to intense examination of the relationship between physicians and companies that sell medical products and devices. Universities, professional societies, and government agencies uniformly condemn such practice and endorse a variety of methods to reduce the likelihood of commercial influence on activities that are designed to be objective.^{2,3}

In 2008, the American Society of Nephrology (ASN) created a committee to review the Society’s policies and practices regarding its interface with commercial interests. The committee submitted its ensuing report to the ASN Council and published a summary of its final recommendations—which were unanimously approved by council—in this issue of *JASN*.⁴

There are four largely separate but contiguous processes whereby commercial interests could influence how physicians provide treatment to patients: conducting research, publishing scientific information, educating practitioners, and developing policy. ASN’s educational efforts comprise the majority of the Society’s interactions with commercial interests and, not incidentally, draw the most national attention from the perspective of potential COI and commercial bias. Thus, ASN conducts its major activity squarely in the sights of those who seek to eliminate the possibility of commercial influence in the process of educating practitioners.⁵

The ASN Committee on Corporate Relations struggled with the meaning and definition of COI. It is widely recog-

nized that everyone has some form of conflict. Although we did not develop a unique definition, we generally agree with the definition proposed by the Institute of Medicine (IOM).⁶ The practical consequence of this definition is that identifying COI should focus on financial conflicts because they are more objective and better suited to regulatory scrutiny. However, although the committee focused its analysis on financial entanglements, we recognize that professional conflicts should be considered when implementing the proposed recommendations.

This emphasis on financial conflicts transforms the focus of bias. We considered one definition of bias as “a conclusion or recommendation based on opinion unsupported by facts.” According to this definition as applied to medicine, almost no recommendation can be totally unbiased. The practical resolution of this matter is to focus on commercial bias, which the committee defines as “an inadequately supported judgment or recommendation about the use of a commercial product.”

The committee made no recommendation regarding the highly controversial issue of continuing medical education (CME) funding. However, the sentiment of the committee is more closely aligned with IOM’s recommendations rather than other recommendations directed at eliminating industry support for CME.^{5,6}

The IOM report makes two important points. First, CME is essential to providing high-quality care to patients and, therefore, its importance is increasing. Second, there is no information on the consequences of making a dramatic shift in funding for CME. Making a major change in how CME is funded in the absence of data will have unforeseen consequences.⁶ The committee generally agrees that any changes should be subject to careful review and testing.

The committee strongly endorses the concept that there should be clear separation between the development of the content of educational programs and the generation of financial support. We are impressed with how well ASN has implemented this policy during the past few years.

Although virtually everyone can agree that there should be no commercial bias in CME activities, there is surprisingly little understanding of the practical implications of this policy. There are two processes for uncovering potential COI and commercial bias. The first is the process of disclosure. The second is the evaluation of presentations by designated observers and participants.

Disclosure is strongly endorsed by all groups. The Accreditation Council for Continuing Medical Education (ACCME) requires disclosure of accredited providers, including ASN. However, what should a speaker disclose? There is wide agreement that a speaker should disclose all financial relationships with commercial entities. In addition, some inter-

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pretations of ACCME regulations would require that speakers disclose financial relationships with governmental and not-for-profit organizations.

What should participants in CME events expect a speaker to disclose? We recommend that speakers be required to clarify at the beginning of their presentations all involvement with commercial interests. To further ensure transparency, moderators should highlight specific information about financial ties to organizations that make products that are relevant to the subjects discussed.

The committee attempted to understand how to identify commercial bias in a presentation. As we discovered, there are no widely accepted criteria for identifying commercial bias. ASN's approach has included an independent review of all slides before a presentation and a (required) question on the CME evaluation form to be completed by all participants pursuing CME credit. In some circumstances, ASN has requested an independent evaluation by selected reviewers. The committee's review produced no clear evidence of commercial bias in any presentation during ASN educational programs. However, we discovered that some participants may have perceived commercial bias when designated observers detected none.

Thus, we are in the unenviable position of trying to eliminate a practice that is evidently rare in ASN educational programs and for which there is no clear definition. Nevertheless, the committee made two recommendations that should heighten awareness of possible commercial bias and begin to assess criteria for its identification. First, ASN should increase its efforts to identify specific individuals to attend presentations and evaluate possible commercial bias. Second, ASN should educate participants about the expectations for disclosure, what constitutes commercial bias in practice, and how to identify potential bias.

The generation of new information must be conducted in an objective fashion. Such objectivity is the foundation of scientific advancement and the development of effective medical therapies. The committee determined that ASN's journal editors follow well-accepted practices for requiring authors to report conflicts. We recommend that the ASN Publications Committee and the journal editors continue to assess developments and adjust their policies and procedures as new opportunities arise. However, we believe the Society must pay more attention to the possibility of commercial bias in the review process.

We recognize that reviewers might have positive or negative predispositions to the conclusions emanating from a given set of data. Some of these predispositions might be influenced by commercial interests. Given the considerable importance of decisions for publication, and that relatively few people are usually involved in such decisions, we recommend that ASN reassess this process. In particular, we recommend that ASN reviewers abide by the same disclosure requirements as the authors they review. This requirement also applies to abstract reviewers. During our evaluation, we realized that the presentation of an abstract reporting the effects of a new product could influence the stock price of the sponsoring company.

All ASN members who participate in the Society's committees, boards, and advisory groups are required to complete a disclosure form. The committee appreciates that different groups might require different kinds of information on potential conflicts. We recommend that ASN's process for reporting and evaluating potential conflicts reflect the specific needs of each group (which includes policy development, education, publications, and grants review) within the context of the Society's overall policy. The committee favors making the disclosure process as simple as possible for each member. To require all members to complete extensive disclosure forms risks an overly bureaucratic process with consequent disincentive to participate in Society activities.

To whom should COI disclosures be made? Disclosed information that resides in a vacuum has no value. Thus, a critical component of disclosure is appropriate review by Society leaders with decision-making authority. These leaders must also inform group members of participants' potential conflicts. The entire process may be group specific, will need to evolve, and should not be imposed by executive fiat.

The process of managing COI is an ongoing activity and will evolve over the next several years and beyond. It will continue to be an important activity irrespective of how national policies of funding CME activities emerge. We live in an age where COI is seemingly encouraged and discouraged. Universities, government agencies, and the public encourage entrepreneurship as a part of our responsibility to develop solutions for medical diseases. However, these same groups, together with professional societies, rightly insist that COI be managed with optimal transparency.

Threading the needle of fairness, transparency, and appropriate privacy in managing conflicts is a daunting task. For this reason—and the fact that this will continue to be a rapidly evolving area—we recommend that ASN develop a group to regularly review the Society's policies and practices for evaluating and managing potential COI and make recommendations for their modification.

ASN's mission is to lead the fight against kidney disease. Members can be assured that there is healthy attention to the process of managing COI and that our Society will be in the forefront of developing ways to evaluate its success.

DISCLOSURES

As is the case with all editorials, the opinions reflected here are the authors and not necessarily the policy of the ASN.

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- See related ASN News, "ASN Policy on Managing Conflicts of Interest," on pages 000–000.