

Disclosure and the Sunshine Act: The Goal of Transparency!

As I have noted in several previous publications and Perspectives, a problem that continues to plague many dental publications and dental continuing education (CE) presentations is a lack of adequate disclosure of potential conflicts of interest by the author or clinician. Disclosure simply reveals any commercial affiliations or financial interests that may have a bearing on the information being disseminated. Unfortunately, all too often, authors and speakers are being supported by a specific manufacturer or commercial entity without any disclosure of this affiliation being made. There is certainly nothing wrong with such sponsorships or financial relationships so long as the reader or listener is apprised of this affiliation through an appropriate disclosure.

To help address this problem in the CE arena, the Food and Drug Administration in 1997 established guidelines on "Industry-Supported Scientific and Educational Activities." The intent of these guidelines was to ensure that any industry-sponsored CE program "is for scientific or educational purposes and not for the purpose of promoting any product and that any discussion of the company's products will be objective, balanced, and scientifically rigorous." Moreover, according to these guidelines, the CE provider, whether it is a dental school or professional organization, shall have full control of the program content and selection of speakers, and that disclosure of any commercial interests will be revealed. These guidelines have, in my opinion, served the profession well for many years as the basis for facilitating ethical continuing dental education through the concomitant full disclosure of any potential conflicts of interest.

Soon we will see full implementation of the Physician Payment Sunshine Act, more commonly known as the "Sunshine Act." This provision is a part of the greater

Affordable Care Act, and its intent is to facilitate even further full disclosure of virtually all types of financial relationships between medical and dental drug and device companies and health care workers, including dentists (see <http://www.healthcare.gov/law/full>). Under this new Act, dental companies are required annually to report "transfers of value" (TOV) made to health care providers, including dentists, to the Centers for Medicare and Medicaid Services (CMS). An IRS Form 1099 will be issued in the amount of the determined TOV value if it exceeds a defined accrued minimum amount per year. Although the full implications of this legislation are not yet fully understood or appreciated by most, it will undoubtedly have a very significant impact on all of us in dentistry and may have significant implications for dental CE as we know it.

Clearly the purpose of this Act is well intentioned: to reduce undue influence by companies on research outcomes and health care decision making, and to facilitate transparency of such relationships for our patients and CE participants. However, the full impact on dental education is still not well understood, and its interpretation could have far-reaching implications for dental CE. Can companies provide products or devices gratis to dental schools for use by participants of hands-on CE courses offered by dental schools? Can dental school faculty individually evaluate materials provided gratis by companies for evaluation for potential inclusion in a dental school curriculum or postgraduate participation type CE course? The answers are not yet entirely clear, but the potential ramifications are significant.

Industry-supported continuing dental education historically has been of vital importance. The dental trade industry deserves considerable credit for the contributions it makes to the betterment of dental care

through such CE support. Without industry support, the number of CE offerings would be substantially reduced. Many manufacturers or other businesses in the dental industry directly sponsor speakers or, better yet, support meetings, speakers, and courses through unrestricted educational grants to various accredited professional organizations. Done with proper disclosure, I believe that this practice is professionally acceptable.

Regardless, when speakers are directly paid or supported by an industrial sponsor or have some financial interest in the commercial entity providing the support, it is the moral obligation of the speaker to reveal such commercial affiliations through proper disclosure to his/her audience if products or devices from that company are included in the presentation. To do otherwise is, in my opinion, unethical and implies a level of objectivity and absence of bias that simply does not exist. Lack of appropriate disclosure of such financial support is simply dishonest and unacceptable.

The Sunshine Act aims to increase the level of transparency and will facilitate appropriate financial disclosures. However, it may have a chilling effect on manufacturer-supported dental CE activities if it is not thoughtfully and fairly administered with regards to policies related to third party payments. Many professional organizations solicit broad industry support for their meetings, programs, and lectures, many of whose speakers may have absolutely no affiliation with the industry sponsor(s). If third party reporting to the CMS is required of professional organizations for this type of general sponsorship, it may have unintended adverse consequences. Hopefully, the provisions of the Sunshine Act will be thoughtfully and rationally applied so that unintended consequences and penalties do not result from a well-intended, but overregulated governmental action.

Adequate disclosure of any potential financial conflicts of interest should also be included in publications solicited or supported by an industrial sponsor. If the author has some financial interest (consultant, paid

lecturer, investor, etc.) in a company whose product is described in a publication, in my opinion, the author also has the professional and ethical obligation to reveal that affiliation through a disclosure statement following the article. Still today, far too many articles appearing predominantly in no charge, dental trade publications are written by authors who clearly have a financial interest with the company whose product is being profiled; yet no disclosure appears. These nonpeer-reviewed publications are informative, highly popular, and broadly distributed. However, all too often, the articles published within these publications are without disclosures and amount to little more than a form of paid advertisement or endorsement, often by a noted clinician.

This need for disclosure also applies to peer-reviewed journals. In particular, disclosure or acknowledgement of funding sources should be revealed at the end of any scientific article that is based on the results of sponsored research. To that end, *The Journal of Esthetic and Restorative Dentistry* instituted this requirement almost 15 years ago. The *Journal* requires a statement of disclosure at the end of each article in which any known perceived conflict of interest may exist. By initiating this practice, we had hoped to set a standard that would encourage other journals and publications to follow suit. However, I am still amazed at the number of new peer-reviewed journals that have been introduced that still do not include a disclosure statement as a matter of routine publication practice. Some journals even include sponsored case reports, with no disclosure of the conflict of interest that exists involving potential affiliations with the case sponsor.

Will full disclosure by authors and lecturers of current financial conflicts of interest totally eliminate bias? Obviously it will not. Our individual experiences with dental companies, their products, and the people associated with these companies will always color our perspectives to some extent whether we have a financial interest or not. However, disclosure when warranted will substantially improve the credibility of both the industrial sponsor and of the author or speaker. Hopefully the Sunshine Act will further this pursuit of

transparency. Proper ethics and honesty warrant it, and our professional obligation to the public we serve demands it.

Harald O. Heymann, DDS, MEd, Editor-in-Chief

Reprint requests: Harald O. Heymann, DDS, MEd, Editor-in-Chief,
Department of Operative Dentistry, UNC School of Dentistry, Chapel
Hill, NC 27599-7450, USA; Tel.: 919-843-9744; Fax: 919-966-5660; email:
harald_heyman@dentistry.unc.edu

Copyright of Journal of Esthetic & Restorative Dentistry is the property of Wiley-Blackwell and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.