

## AFP's Conflict of Interest Policy: Disclosure Is Not Enough

JAY SIWEK, MD, *Georgetown University Medical Center, Washington, District of Columbia*

► See related Letter to the Editor on page 151.

Medical journals go to great lengths to ensure that authors disclose potential conflicts of interest. In research journals, financial ties between authors and the makers of drugs and medical devices are inevitable because more than half of research is funded by the pharmaceutical industry.<sup>1</sup> However, just about all medical journals permit authors of review articles and editorials to also have such ties. At *American Family Physician (AFP)*, we do not. Our 25-year-old policy is sometimes questioned or misunderstood because it is rare among medical journals. However, I think it is an important way to guard against untoward influence and intentional or unintentional bias in our clinical review articles.<sup>2</sup>

Our conflict of interest policy states: "To avoid bias or the perception of bias, *AFP* will not consider manuscripts sponsored directly or indirectly by a pharmaceutical company, medical education company, or other commercial entity, or those written by an author who has a financial relationship with or interest in any commercial entity that may have an interest in the subject matter of the article."<sup>3</sup> Note that this policy is not restricted to specific drugs or devices to which the author may have ties; it covers the topic of the article and a commercial company's potential interest in that topic. Because our review articles are developed for the continuing medical education (CME) of approximately 175,000 readers, we take seriously our obligation to ensure unbiased content. However, we recognize that conflicts of interest are only one potential source of bias, and that intellectual bias (e.g., strongly held opinions, often specialty specific) can also unduly influence the presentation.<sup>4</sup>

We realize that many physicians see nothing wrong with drug company-sponsored

talks or CME articles. So, to better explain the reasoning behind our conflict of interest policy, *the accompanying table* outlines some of the arguments typically given to justify disclosure as a sufficient safeguard against bias, and the reasons we think disclosure is not enough.<sup>2,5-17</sup> The Institute of Medicine,<sup>18</sup> the American Medical Association,<sup>19</sup> and the Association of American Medical Colleges<sup>20</sup> have all recently issued reports calling for elimination or limitation of industry-sponsored CME. For similar reasons, the medical editors of *AFP* believe that CME should not have any ties to makers of drugs or medical devices. In addition, *AFP* does not permit placement of advertising next to related clinical content, does not place advertisements within review articles, and does not accept drug company-sponsored supplements.

The author thanks Dr. Adriane Fugh-Berman for her review of an earlier version of this editorial.

EDITOR'S NOTE: Dr. Siwek is editor of *AFP*.

*AFP's* conflict of interest policy is independent and different from the American Academy of Family Physicians' conflict of interest policy.

Address correspondence to Jay Siwek, MD, at [siwekj@georgetown.edu](mailto:siwekj@georgetown.edu). Reprints are not available from the author.

Author disclosure: No relevant financial affiliations.

## REFERENCES

1. Dorsey ER, de Roulet J, Thompson JP, et al. Funding of US biomedical research, 2003-2008. *JAMA*. 2010;303(2):137-143.
2. Fugh-Berman A, Siwek J. Compromising the medical literature: the hidden influence of industry-biased articles. *Am Fam Physician*. 2011;84(5):489-490.
3. Conflict of interest form. Authors' guide. *American Family Physician*. <http://www.aafp.org/journals/afp/authors/guide/coi.html>. Accessed October 1, 2013.
4. Lo B, Ott C. What is the enemy in CME, conflicts of interest or bias? *JAMA*. 2013;310(10):1019-1020.
5. Ellison JA, Hennekens CH, Wang J, Lundberg GD, Sulkes D. Low rates of reporting commercial bias by physicians following online continuing medical education activities. *Am J Med*. 2009;122(9):875-878.
6. Blumenthal D. Doctors and drug companies. *N Engl J Med*. 2004;351(18):1885-1890.
7. Cain DM, Loewenstein G, Moore DA. The dirt on coming clean: perverse effects of disclosing conflicts of interest. *J Legal Stud*. 2005;34:1-25. ►

**Table. Reasons Why Disclosing Conflict of Interest May Not Be a Sufficient Safeguard Against Bias in Clinical Review Articles and Editorials**

*Arguments for why disclosure is sufficient*

*Counterarguments*

**Arguments from industry, professional medical organizations, medical journals, etc.**

Disclosure alerts readers to the potential for bias and allows them to evaluate the article in that light. Also, studies show that physicians do not perceive industry-sponsored CME activities to be biased.<sup>5</sup>

Readers are generally not trained to evaluate content for subtle bias or recognize “spin” in clinical presentations (e.g., word choice, framing of content, topic selection). Most physicians are not familiar with every drug in a company’s portfolio, so disclosure of company ties is often perfunctory and uninformative. Promotion of a drug often starts years before the drug comes on the market, by promoting a disease, a mechanism, or problems with current therapies. It is not possible to detect bias for a drug that has not been marketed yet.

The social science literature suggests that physicians may have difficulty detecting bias in CME.<sup>6</sup> It is unfair to put the burden on readers, who generally expect content to be unbiased.

Disclosure complies with the principle of transparency, and indicates compliance with proper protocol.

Disclosure may convey a false sense of security about the content: “If they’re honest enough to disclose their ties to industry, the presentation must also be honest.” Disclosure may paradoxically increase an audience’s trust in the information provided, and the likelihood of bias.<sup>7-9</sup>

Disclosure gives CME providers the opportunity to address and “resolve” the conflict of interest via peer review, adherence to “best evidence,” or some other mechanism specified by the Accreditation Council for Continuing Medical Education.<sup>10</sup>

Peer reviewers are not trained to recognize marketing messages, and may not always spot biases in the presentation (especially if they are subtle and based on such things as word choice, framing of content, or topic selection). Presentations on the prevalence or severity of a condition, “emerging” therapies with a novel mechanism of action, or problems with competing therapies are unlikely to provoke suspicion of bias.

Biased presentations can, and usually do, incorporate best evidence, but may be spun to highlight the advantages of targeted drugs or the disadvantages of competing therapies.<sup>11</sup>

Once an article has been written, it can be difficult to alter its slant and tone, or to remove subtle bias, much less to change the choice of topic itself.<sup>12</sup> Once biased information enters the medical literature, it can be difficult to alter its distorting effect on the evidence base.<sup>2,13</sup>

**Arguments from speakers/authors providing CME**

“The clinical views I present are mine and mine alone—the drug/device company did not tell me what to say.”

In many cases, the drug/device company *does* tell their speakers and authors what to say and write. The company also provides them with slides, and writes or reviews and edits the presentation.<sup>14</sup>

Even if this is not the case, the presenter has been courted and selected for a speaker’s bureau or authorship because his or her views align well with the company’s marketing messages. Speakers who stray too far from a company-friendly viewpoint do not stay on a speaker’s bureau for long.<sup>15,16</sup>

“I have ties to so many companies, I can’t be biased in favor of any one of them.”

Such presenters are often referred to as “key opinion leaders” who have been courted, groomed, and well paid by drug/device manufacturers.<sup>15</sup> Their views align well with multiple companies’ marketing messages (e.g., an expert on chronic obstructive pulmonary disease who has ties to the manufacturers of every major medication for the disease). Any presentation elevates the apparent importance of the topic, and each company shares in the downstream benefit of increased diagnosis and treatment. Also, discourse is limited to competing branded drugs. Older drugs, less marketed drugs, generics, and nonpharmacologic therapies may not be discussed.

“My presentation doesn’t even mention a specific drug or device, so there can’t possibly be any bias.”

Presenters are often used to highlight the importance of a certain disease/clinical condition, making it seem more prevalent or severe than previously thought. It has been said that “Pharma doesn’t hire doctors to sell drugs; that’s a drug rep’s job. Pharma hires physicians to sell diseases.”<sup>17</sup> For instance, how often was restless legs syndrome discussed before the first drug approved to treat it was being developed? Restless legs syndrome seemed to suddenly become a scourge and epidemic. And now that generic colchicine is no longer available, presentations to physicians on gout, funded by the maker of the 50-fold more expensive brand-name version, have markedly increased.

Presenters may focus solely on diagnosis, not treatment; however, this can lead to increased diagnosis and, ultimately, increased treatment.

Presenters may focus solely on pathophysiology, not treatment; however, a presentation on incretin physiology and dipeptidyl-peptidase-4 inhibition can lay the groundwork for promoting diabetes treatments that are based on these mechanisms of action.

*CME = continuing medical education.*

*Information from references 2, and 5 through 17.*

8. Loewenstein G, Sah S, Cain DM. The unintended consequences of conflict of interest disclosure. *JAMA*. 2012;307(7):669-670.
9. The PLoS Medicine Editors. Does conflict of interest disclosure worsen bias? *PLoS Med*. 2012;9(4):e1001210. <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001210>. Accessed October 1, 2013.
10. Accreditation Council for Continuing Medical Education. How does a provider implement a mechanism for resolving conflicts of interest? November 11, 2011. <http://www.accme.org/ask-accme/how-does-provider-implement-mechanism-resolving-conflicts-interest>. Accessed October 1, 2013.
11. Spielmans GI, Parry PI. From evidence-based medicine to marketing-based medicine: evidence from internal industry documents. *J Bioeth Inq*. 2010;7:13-29.
12. Bauchner H, Fontanarosa PB. Restoring confidence in the pharmaceutical industry. *JAMA*. 2013;309(6):607-609.
13. Moynihan R. It's time to rebuild the evidence base. *BMJ*. 2011;342:d3004.
14. Fugh-Berman A. The corporate coauthor. *J Gen Intern Med*. 2005;20(6):546-548.
15. Moynihan R. Key opinion leaders: independent experts or drug representatives in disguise? *BMJ*. 2008;336(7658):1402-1403.
16. Carlat D. Dr. drug rep. *New York Times*. November 25, 2007. <http://www.nytimes.com/2007/11/25/magazine/25memoir-t.html?pagewanted=all&r=0>. Accessed October 1, 2013.
17. Big pharma, bad medicine [forum commentary]. *Boston Review*. May 1, 2010. <http://bostonreview.net/fughberman-selling-diseases>. Accessed October 1, 2013.
18. Lo B, Field MJ, eds.; Institute of Medicine. *Conflict of Interest in Medical Research, Education, and Practice*. Washington, DC: The National Academies Press; 2009. <http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx>. Accessed October 1, 2013.
19. Council on Ethical and Judicial Affairs. Financial relationships with industry in continuing medical education (A-11). Chicago, Ill.: American Medical Association; June 2011. <http://www.ama-assn.org/resources/doc/ethics/ceja-1a11.pdf>. Accessed October 1, 2013.
20. Industry funding of medical education: report of an AAMC task force. Washington, DC.: Association of American Medical Colleges; 2008. <https://members.aamc.org/eweb/upload/Industry%20Funding%20of%20Medical%20Education.pdf>. Accessed October 1, 2013. ■

# Straightforward. Accessible. Manageable.

TAKE THE GUESSWORK OUT OF SAMS.

## Register early to save \$40

### Course Date / Subject / Location

- April 12 / Cerebrovascular / Las Vegas, NV
- April 13 / Preventive Care / Las Vegas, NV
- July 18 / Asthma / Myrtle Beach, SC
- July 19 / Diabetes / Myrtle Beach, SC
- Sept. 20 / Coronary Artery Disease / Chicago, IL (Rosemont)
- Sept. 21 / Childhood Illness / Chicago, IL (Rosemont)
- Sept. 20 / Hypertension / Albuquerque, NM (Santa Ana Pueblo)
- Sept. 21 / Health Behavior / Albuquerque, NM (Santa Ana Pueblo)
- Oct. 11 / Hospital Medicine / Hershey, PA
- Oct. 12 / Heart Failure / Hershey, PA
- Oct. 22 / Diabetes / Washington, D.C.
- Oct. 23 / Asthma / Washington, D.C.
- Oct. 24 / Preventive Care / Washington, D.C.
- Oct. 25 / Health Behavior / Washington, D.C.
- Nov. 15 / Heart Failure / Las Vegas, NV
- Nov. 16 / Well Child Care / Las Vegas, NV

Attend an AAFP **SELF-ASSESSMENT MODULE WORKING GROUP** and complete the knowledge assessment portion of your MC-FP Part II with ease.

In one day, assess and review the 60 core competency questions, led by expert family physicians currently working in the field, and decide the best answer as a group. The AAFP will report your successful knowledge assessment score to the ABFM on your behalf.

Participate with your colleagues in a distraction-free, focused work environment that fosters interaction and promotes collaboration, while you earn CME\*.

Prices start at \$225 for AAFP members  
[aafp.org/completesams](http://aafp.org/completesams)  
**(800) 274-2237**

\*To complete the SAM process and earn CME, you must also complete the clinical simulation on the ABFM website within one year (separate fee to the ABFM required).

ONE DAY.  
 DONE.

