The pudding, the beef, and conflicts of interest

Robert M. Sade, MD

See related letter to the Editor on pages 258-9.

The ideas presented in a recent editorial in the *Journal*, “Managing Conflicts of Interest,”¹ are well illustrated by the publication of a recent article and responses to it.

Recently, Flameng and coworkers² described a new process for preserving bovine tissue for use in a mitral valve bioprosthesis. The study was sponsored (that is, it was paid for) by a manufacturer of bioprosthetic valves. This fact created a conflict of interest (COI) for the investigators, because the primary interest of the investigators is advancing the science underlying valve replacement surgery, which requires objective reporting of well-designed studies, but a secondary interest is also present, namely the financial well-being of the sponsoring company. This secondary interest creates a COI by introducing the possibility of compromising the primary interest through flawed design or biased reporting of the study.

Many important biomedical advances have come from the highly fruitful alliance between medicine and industry. COIs that arise from sponsored studies are common and are not inherently wrong. The reason for concern when a COI is present, however, is that the COI introduces the possibility of bias or imbalance in the design and execution of the study and in the reporting of its results.

A recent editorial of which I was a coauthor¹ focused on how a journal should deal with such COIs—it was accompanied by modifications in the *Journal*’s “Guide for Authors.”³ Authors are required to fill out a “Disclosure of Potential Conflicts of Interest” form, and editors and reviewers decide whether a COI is present. If so, reviewers are asked to be especially alert to the possibility of bias or imbalance in the study. As experts in the particular focus of a study, reviewers are better positioned than most readers to detect subtle biases in the manuscript. Reviewers give feedback to authors that is generally aimed at improving their article; in cases

of COI, however, the feedback especially focuses on reducing or removing any bias or imbalance in the report.

Readers are also given relevant disclosure information to aid their own critical analysis, but if the reviewers have done a thorough job of vetting the manuscript, any problems related to the COI will have been reduced or eliminated in the final article. Another recent innovation is an Editorial Commentary that accompanies each published article; this is another means of transferring the burden of detecting problems from the reader to the editorial process. These commentaries provide additional background and point to strengths and flaws in the article.

Schmoker’s Editorial Commentary⁴ that accompanied Flameng and coworkers’ article² identified problems related to their COI. One problem was in the design of the study: materials chosen as controls were too limited, and in the commentator’s view objective outcome measures were insufficient, making the study design unbalanced. At the stage of submission for publication, of course, nothing can be done to change the study design, other than to decide whether the omissions so seriously flaw the study that it should not be published, which was not the case for this report.

In the original article’s text, a descriptive phrase carries a suggestion of bias. The sponsoring company’s current bioprosthetic valve was used as the control with the statement that “many surgeons consider it one of the ‘standard of care’ valves.” In the Conclusions section, however, this portrayal is more definitive: the control valve is presented as “currently considered the standard of care.” Really? In the earlier statement, only “many surgeons” considered it to be the standard of care, but in this conclusion, it has become *the* standard of care. This suggestion of subtle bias could have been identified by reviewers and modified before publication, but it was not. It was, however, identified in Schmoker’s commentary. Review processes and editorial commentaries are complementary modalities that are well-suited to detect and safeguard against biases and imbalances related to COIs.

Subsequent to publication of the article, a letter from Flameng and Meuris⁵ provided a spirited defense of their article against Schmoker’s critical commentary,⁴ and Schmoker has responded to their arguments.⁶ The point-counterpoint discussions embodied in these

From the Division of Cardiothoracic Surgery, Department of Surgery, Institute of Human Values in Health Care, Medical University of South Carolina, Charleston, SC.

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Address for reprints: Robert M. Sade, MD, Department of Surgery, Medical University of South Carolina, 114 Doughty St, Suite 277, MSC 295, Charleston, SC 29425 (E-mail: sader@muscc.edu).

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exchanges illustrate the importance of such academic discourse in alerting readers to the nuances of issues surrounding COI. Not every editorial decision about COI will be correct, but discussions such as these will better inform our readers and our surgical community, with the hope of improving appreciation of the complexities of COI.

Despite some flaws related to company sponsorship, Flameng and coworkers' article² was considered to be worthy of publication, and we agree with that judgment. Schmoker's Editorial Commentary identified issues related to the authors' COI and brought them to light for the consideration of readers who may be less expert in this area.

The *Journal* hopes to ensure that every article that it publishes is free of bias and imbalance to the extent possible,

regardless of the funding source. The current COI policy aspires to that goal.

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