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EDITOR'S PAGE

Challenges in Dealing with Conflict of Interest

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The issue of conflict of interest has long been a point of discussion for all aspects of cardiovascular medicine and surgery (including research, education, guidelines etc). The transfer of resources from industry to medical parties has always had the potential to induce bias. However, the focus upon potential or existing conflict has intensified greatly over the last several years. This has certainly been true in the field of structural heart disease, where innovation has been exponential and involved the close collaboration of industry and the medical profession. As is so often the case, it is easier to identify a potential problem than it is to resolve it. Actions taken to deal with conflict of interest have not been without negative unintended consequences. At the current time, approaches to the identification, reporting, and enforcement of existing rules for behavior regarding conflicts are variable, imperfect, and continue to evolve.

There has always been a close interaction between the professional medical community and medical industry. We physicians need drug and device manufacturers to deliver effective products to diagnose and treat our patients. Industry has also been the engine for converting basic research discoveries into clinical products. Finally, industry has traditionally provided support for our research and educational activities. Similarly, industry has depended upon the medical profession in a number of ways. The medical community has identified and defined the needs for new products and provided targets for therapy. We in medicine have been responsible for validating the efficacy of new products and determining their optimal clinical application. Of course, industry is completely dependent upon physicians to use their products.

The interaction between the medical profession and industry has had many advantages. It has enhanced innovation in developing drugs, biologics, devices, and basic science. Collaboration between medicine and industry has fostered knowledge creation and driven the translation of discoveries into products. The support of education has enabled the more rapid dissemination of new knowledge and procedures into clinical care, reduced the application of less effective therapies, and provided education regarding the underlying biologic mechanisms of pathology and its management.

The interaction between medicine and industry has clearly been beneficial to society. There are a number of effective therapies that have resulted from the collaboration, including statins, renin-angiotensin-aldosterone inhibitors, pacemakers/defibrillators and, most recently, transcatheter aortic valve replacement. Of course, many other examples exist. In addition, one need only look at the reduction in deaths from cardiovascular disease over the past several decades, much of it due to new pharmaceuticals and procedures, to appreciate the benefits to society. A decrease in the number of deaths from cancer, and near elimination of deaths from HIV-AIDS further evidence the value that the interaction of medicine and industry has conveyed in the past.

Given that the collaboration of medicine with industry is generally beneficial, it is not surprising that such interactions are nearly ubiquitous. Thus, surveys have shown that 94% of physicians report some relationship with industry.[1] The reception of gifts was reported by 83% of physicians while 28% received payments for professional services such as consulting or research participation. Of interest, 60% of those with relationships were involved in medical education while 40% participated in creating practice guidelines. Accordingly, the overwhelming majority of doctors were involved in a situation that exposed them to some risk of the appearance of or actual bias. Of note, 80% of physicians who tweeted had potential conflicts of interest, so social media is not exempt.[2] In terms of education, industry support of education amounted to nearly $5 billion, or almost half of all spending on Continuing Medical Education (CME).[3]

Conflict of interest has been defined as a situation in which a person is or appears to be at risk of acting in a biased way because of personal interests. Conflict of interest is almost always thought of in financial terms, specifically that behavior may be biased by money or goods. Every form or report that I have ever been asked to complete in regard to potential conflict of interest has dealt only with monetary issues. However, the desire for fame, recognition, or professional advancement can often be a more potent stimulus to bias than any monetary gain. In my prior editorial experience, the appearance of potential conflict and bias was more often encountered related to professional competition than to finances. The focus on money as a source of conflict can distort the importance of this factor and neglect the impact of professional competition and other sources of potential bias.

Although the issue of conflict of interest has been long recognized, it has received progressively increasing attention for the last decade. In fact, the number of articles addressing medical conflict of interest has roughly quadrupled since

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1990.[4] It has been suggested that relations with industry can lead to patterns of clinical practice that increase the cost of care. Concern has been expressed in regard to the potential for bias in research, medical education, and guideline documents. This has led to the publication of medical/industry Codes of Ethics by numerous organizations, including the American Medical Association, American Association of Medical Colleges, numerous professional societies, and even the Pharmaceutical Research and Manufacturers of America. Both the Institute of Medicine and the U.S. Preventive Services Task Force have addressed conflict of interest in guideline documents. Many medical schools and research institutions have generated their own policies on conflict of interest in research; however there is wide variability in these policies between institutions, and very few have any stipulated penalty should the policy be violated.[5] Interestingly, surveys of patients and the general public have indicated that awareness among these groups of conflict of interest was low, and that acceptability was greater for office-use professional gifts than for personal gifts.[6]

Concern for potential conflict of interest due to industry relations culminated in the recent legislation termed the Sunshine Act. This legislation covers all medical drug/device companies and all medical practitioners. The statute requires that all payments or transfers of value worth $10 or more be reported to be published in a document that is open to the public. The implications of this legislation are obvious, and have cast relations with industry in a different light than in prior years.

Recently an article appeared in the literature that seemed to me to provide a very rational construct for viewing different types of medical-industry relations. Latten and colleagues[7] proposed that these relationships could be placed in four categories. Philanthropic relations would consist of a one way transfer of resources, while transactional relations would consist of bilateral exchanges of resources. Integrative relations would involve the exchange of key resources in a conjoined fashion, while transformational relations would be the most in-depth and consist of shared learning rather than mere exchange of resources. In this formulation, philanthropic relations would be most susceptible to bias and require most evaluation while transformational relations would be the most intense and most likely to yield benefit for society. This construct seems to me to provide a good basis for viewing medical interactions with industry.

The major approach to resolving potential conflict of interest and bias has thus far consisted of disclosure. The assumption has been that full disclosure of all potential conflicts would enable the audience to evaluate any possible bias. Accordingly, no communication would be disqualified if all relations were disclosed. However, the requirements for and nature of disclosure vary enormously among various agencies, especially among medical publications. In fact, it is very unusual for any agency to have in place any mechanism to verify whether or not disclosures are complete or accurate.[5] Therefore, while disclosure may be the best and most feasible approach to dealing with potential bias, it is at best imperfect as currently applied.

The attention given to and actions being taken in regard to conflict of interest have the potential to result in a number of negative unintended consequences. The actions can create a barrier between inventors and industry, inhibiting the progression of research and/or translation of the findings. Most universities prohibit the participation of inventors in the subsequent research evaluation of their innovations. Reduction of support of medical education due to conflict of interest concerns has the potential to reduce access to new knowledge, especially among those who are most needy such as those in the developing world. Reduced support of CME can divert money into product specific programs that are even more susceptible to bias. Policies restricting the participation of individuals in the formation of guidelines can result in writing panels that lack expertise. The same can be said of restricting reviewers from the evaluation of manuscripts submitted for publication. The conflict of interest policies do create additional administrative burden. Finally, the attention and actions regarding conflict have implications regarding the ability of physicians to detect bias or succumb to gifts. In a sense, this is somewhat belittling to the medical profession. It implies that physicians can be easily duped and not recognize conflict and bias. I believe that the opposite is true, and that physicians are attuned to and can detect bias very well. Similarly, I do not believe that the behavior of most physicians can be dictated by the provision of financial or other resources, especially those in the range of $10. So efforts to eliminate potential bias due to conflict of interest is a double-edged sword.

In conclusion, conflict of interest remains a concern in medicine, and one whose impact and resolution continues to be defined. It is clear that relations between industry and physicians are ubiquitous, but are only one source of conflict. In general, relations between medicine and industry have been very beneficial to society. However, these interactions are capable of introducing bias, and it is important that steps be taken to minimize such an outcome. Currently, disclosure is the primary manner in which potential conflict of issues are addressed, but the application of disclosure measures is very variable and incomplete. In addition, it must be recognized that actions to limit conflict of interest can have important negative unintended consequences. One thing is certain regarding conflict of interest, current approaches are imperfect, and an optimal, rational approach continues to evolve.

Disclosure statement

The author has no conflicts of interest to disclose.

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