Counterpoint: Full Disclosure Where Is the Evidence for Nefarious Conflicts of Interest?
Robert M. Sade
DOI: 10.1016/j.athoracsur.2011.05.078

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://ats.ctsnetjournals.org/cgi/content/full/92/2/417
Counterpoint: Full Disclosure—Where Is the Evidence for Nefarious Conflicts of Interest?

Robert M. Sade, MD

Department of Surgery and Institute of Human Values in Health Care, Medical University of South Carolina, Charleston, South Carolina

Recent years have seen increasing focus on relations between physicians and industry, particularly pharmaceutical and device companies, and the conflicts of interest (COIs) that might arise from them [1]. Specific abuses of such relationships have often garnered national attention through scholarly journals and public communications media [2, 3].

For related article, see page 413

In May 2009, the American Association for Thoracic Surgery (AATS) and The Society of Thoracic Surgeons (STS) jointly adopted a report establishing standards for proper relationships between individual cardiothoracic surgeons and industry [4, 5]. One of the standards addresses the question of disclosure: “Members should disclose their own or their institutions’ financial relationship with the manufacturer of a drug or device whenever clinical research or experience with a particular procedure or device is presented at a meeting or is published.”

This standard is stated in broad terms, and the precise meaning of “disclose” is not spelled out. The AATS and the STS require that all authors must disclose relationships with companies that could constitute a COI before their papers can be presented at annual meetings [6, 7]. Both organizations report only the name of the possibly conflicted author, the company with which he has a relationship, and the nature of the relationship. No other details are published in the annual meeting program.

The AATS and STS official journals, The Annals of Thoracic Surgery (ATS) and Journal of Thoracic and Cardiovascular Surgery (JTCVS), respectively, have specified the details of industry relationships that must be disclosed before a paper will be published. If a conflict is disclosed, ATS places a text box on the title page of the published article: “Dr X discloses that he/she has a financial relationship with company Y.” No additional details are provided [8]. The JTCVS disclosure statement requires reporting not only the name of the company with which a conflict exists and the nature of the relationship, but also the dollar amount received by the author—other details, such as the duration of the relationship, are omitted [9].

The published disclosures of COIs for these annual meetings and journal publications include neither dollar amounts nor duration of the reported relationships.

Should Full Disclosure Include Dollar Amounts and Relationship Duration?

Cardiothoracic surgeons are familiar with the requirements of disclosure of COIs in presentations and in publications, as they are ubiquitous in presentations at meetings and papers in journals. In answer to the question of whether increased levels of disclosure are needed, J. Peter Murphy responds in the affirmative in the accompanying article, and argues that we should add dollar amounts and duration of relationships to current disclosure requirements [10]. He cites the work of Jerome Kassirer approvingly in support of his position. This is quite appropriate, as Kassirer has been a vocal leader of the critics of relations between physicians and industry. Yet, he is not an admirer of disclosure in general: “We must be highly skeptical about the most popular approach to managing conflicts of interest, namely, disclosing the relationships [11].” There is good reason for Kassirer’s skepticism. Disclosures of conflicts are rarely verified, making their accuracy unreliable; listeners and readers are often unable to identify biased information because of their lack of expertise; and attention may be distracted from bias by implying that the disclosure itself diminishes the speaker’s or author’s bias [2]. Moreover, the plethora of disclosures at conferences and in publications may dull sensitivity and interest in them by virtue of frequent repetition, inuring receivers of the information to the relevance of disclosures [12].

Much anecdotal information has been published about biased presentations and publications [13]. Yet, the gravity of problems related to inaccurate, unbalanced, or prejudicial presentations is poorly understood owing to the paucity of systematic investigations of the frequency and impact of such presentations.

Arguments Against Disclosure of Relationship Duration and Payments

Dr Murphy makes several observations with which we agree: COIs are not related only to money, but also to nonfinancial considerations such as career advancement and academic achievement; the collaboration between...
industry and physicians has been highly productive and beneficial for patients in the past; some, but not all, financial interactions between industry and physicians are unseemly or worse; hard evidence for the existence or severity of the problem is in short supply; and, finally, the status quo is unsatisfactory.

In making the case for increasing disclosure requirements to include dollar amounts and duration of relationships, however, Murphy cites what he understands to be the two “legitimate” arguments against such a requirement: it is an intrusive, gratuitous invasion of privacy, and collecting the data and reporting it are difficult and costly. These are legitimate arguments, but they seem of minor importance compared with two much more important counterpoints to the case for requiring more detail in disclosures: the real danger of slowing if not interrupting the highly productive research and innovation that has come from physician-industry collaboration over the last half-century, and the nearly complete absence of reliable evidence that this collaboration or any other interactions between physicians and industry poses a serious threat to patient safety.

**Productive Research and Innovation**

To appreciate the progress that has been made through physician-industry collaboration, one need only mention the pump oxygenator developed by Dr John Gibbon collaborating with engineer Thomas Watson of IBM, the cardiac valve prosthesis developed by Albert Starr working with engineer Lowell Edwards (resulting in the creation of the highly successful Edwards Laboratories), and external, then implantable, pacemakers developed by Dr C. Walton Lillehei jointly with engineer Earl Bakken, creator of Medtronic. These pairs represent collaboration between heart surgeons and commercial engineers, each of which led to a major advance in heart surgery. Many other highly productive alliances could be cited in other surgical specialties, such as orthopedics and neurosurgery.

The contributions to human welfare by cooperative work between physicians and industry—both pharmaceutical and device companies—have been enormous. In the last few decades, fully half of the reduction in deaths due to coronary artery disease can be attributed to collaborations that have led to improvements in evidence-based therapies [14]. Indeed, such advances would not have been possible without merging the knowledge and skills of businessmen, engineers, and technical experts in industry with the clinical expertise of physicians, whose knowledge of clinical needs and the ways in which drugs and devices interact with the human body is indispensable to biomedical innovation. The higher the barriers that are erected between the creative minds of industry and of medicine, the less innovation and improvement of human health are likely to occur. Admittedly, there is little clear and convincing evidence that physician-industry collaboration has been harmed by current disclosure requirements, but given the amply proved benefits of such alliances and the absence of scientific evidence that they cause harm, the burden of proof rests on those who wish to impose additional regulation.

**Absence of Evidence**

The facts underlying the national debate on relations between industry and physicians are seen to be meager when stripped of assumptions grounded in intuition and unsupported assertions. Murphy clearly documents much negative publicity in the media, some emanating from Congress, about disturbingly high levels of payment from industry to some physicians. Beyond that, very little hard evidence indicates that physician COIs vis-à-vis industry pose a serious threat to health care. Nearly all of the experimental research underlying this concern comes from the psychology and sociology literature, from which physician behavior is projected from investigations carried out in nonmedical contexts. Most of the remaining evidence comes from surveys of the views and experiences of physicians, residents, and patients [10]. Both of these data sources have low probative value.

The ranking and relative value of evidence types has been investigated and described by several groups, such as the US Preventive Services Task Force (USPSTF) [15] and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group [16]. Rankings of the relative value of different kinds of evidence may be helpful in thinking about the question at hand (Table 1). All of the evidence supporting the need for a high level of scrutiny and regulation of physician-industry relations falls into code D, quality of evidence = very low, suggesting that existing data are far from dispositive of this issue. Moreover, the lowest of five ranks on the USPSTF effectiveness of evidence scale is authoritative statement: “Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees [17].” We ought to exercise extreme caution in using currently available information, all of which is of low quality, to make important policy decisions.

Dr Murphy agrees that the data supporting his position is weak and points to the difficulty of carrying out randomized controlled trials in this area, implying that the only alternative to anecdotes, surveys, expert opinions, and extrapolations from experiments in unrelated fields is a randomized controlled trial. There are many other kinds of evidence, however, such as nonrandomized prospective and retrospective studies of various types. In fact, one particular study that is both feasible and relevant to the debate has not been done. It is related to the critical central issue, the reason why anyone cares about physicians’ COI: the possibility that COIs cause harm to patients. Harm to patients should be the primary outcome measure in studies of the concerns about COI, disclosures, and conflict management. Yet, no study, retrospective or prospective, has been carried out to
examine the effects of physicians’ COIs on the outcomes of patient care. In the absence of this critical information, no rational policy to regulate physician-industry relations is possible.

One of the most widely cited and exhaustively researched papers on investigations of the effects of relations between physicians and the pharmaceutical industry was published in 2000 and states this about the outcomes of such relations: “No study used patient outcome measures [18].” To fill in that information for subsequent years, this writer undertook an extensive search of the biomedical literature and was able to find only a single paper that addressed, albeit indirectly, COI and clinical outcomes. It is a meta-analysis of patient outcomes after autologous chondrocyte implantation, comparing commercially funded with independently funded studies [19]. The authors found no difference in patient outcomes between the two groups. Although this evidence is from meta-analysis, and therefore of only intermediate quality, it does not support a need for intensified regulation of physician-industry relations.

Until we have well-designed and executed studies of physician-industry COI that use the outcomes of patient care as the primary outcome measure, we will not be able to weigh the benefits to patients (known and documented medical innovation and improved health outcomes) against the harms (as yet undocumented compromise of patient care outcomes caused by physicians’ biases in prescribing and using drugs and devices due to COI).

Without such studies, we cannot create rational policy and law on physician-industry relations—that is, we cannot rationally decide whether optimal health care can be achieved most reliably by strengthening disclosure requirements, as Murphy suggests, or by encouraging collaboration between physicians and industry by breaking down barriers rather than building them. To this writer, the latter, although politically unpopular, seems the more reasonable course.

---

Table 1. Levels of Evidence and Need for Further Research

<table>
<thead>
<tr>
<th>Code</th>
<th>Quality of Evidence</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>High</td>
<td>Further research very unlikely to change our confidence in estimate of effect. Several high-quality studies with consistent results. In special cases: one large, high-quality multicenter trial.</td>
</tr>
<tr>
<td>B</td>
<td>Moderate</td>
<td>Further research likely to have important impact on our confidence in estimate of effect and may change estimate. One high-quality study. Several studies with some limitations.</td>
</tr>
<tr>
<td>C</td>
<td>Low</td>
<td>Further research very likely to have important impact on our confidence in estimate of effect and is likely to change estimate. One or more studies with severe limitations.</td>
</tr>
<tr>
<td>D</td>
<td>Very low</td>
<td>Any estimate of effect is very uncertain. Expert opinion. No direct research evidence. One or more studies with very severe limitations.</td>
</tr>
</tbody>
</table>

Source: GRADE (Grading of Recommendations Assessment, Development and Evaluation) Working Group 2007 (modified by the EBM Guidelines Editorial Team) [20].

Dr Sade’s work was supported in part by the South Carolina Clinical and Translational Research Institute, Medical University of South Carolina’s Clinical and Translational Science Award Number UL1RR029882. The contents are solely the responsibility of the author and do not necessarily represent the official views of the National Center for Research Resources or the National Institutes of Health.

References