Third-Party Vendors of Continuing Medical Education and Health Providers in Diabetes: A Deepening Conflict of Interest

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"Dear Doctor: You are invited to attend the annual clinical update on.... To attend this meeting you ***must*** *book your travel with.... Travel at least six weeks in advance.... Travel will offer you one itinerary. You* ***must*** *respond within 24 hours of receipt of the itinerary to request amendments to the itinerary. You will be offered a nonrefundable airline ticket that cannot be modified. After that, any further changes in the travel schedule* ***must be made at your personal expense.*** *Should you wish to change your travel at any time after the ticket has been issued, you will be* ***required to pay any penalties and adjustments.*** *"* (The bold print was in the original letter.)

I received this letter from a third-party vendor for a pharmaceutical company. The letter invited me to the pharmaceutical company's annual scientific update about advances related to their diabetes-related product. I read the letter three times and put it aside. A few weeks later, I received a call from this vendor. The caller wanted to know why I had not responded to the invitation. I told her that my schedule did not allow me to accept travel on such stringent terms. As a practicing physician, I might have to suddenly alter my plans. "Well," she responded, "according the AMA guidelines, you should be required to pay for those changes yourself."

Diabetes has become a much more important business area for pharmaceutical companies over the past 10 years. This has led to rapid growth in the number of companies involved with this clinical discipline and in interactions between companies and diabetes health care professionals. As ethical questions regarding health care professionals' interactions with pharmaceutical companies have increased over the past decade, the details of these interactions have become more regimented and regulated.

With more companies involved in the field, competition among companies to attract health care professionals' interest in and support of their products is increasing. Thus, as reviewed in a recent *Wall Street Journal* article,[1] companies are seeking opportunities to get their messages to health care professionals in a focused and positive fashion. One way to do this is through scientific meetings, which the companies hold at central locations, usually hotels or resorts.

In the field of diabetes, these scientific updates, usually held by each company annually, have become an important focus of interest for health care professionals and pharmaceutical companies alike. Aside from the annual scientific meetings of the American Diabetes Association, these symposia are often among the most active opportunities for updates on information about specific topics or product areas. They also afford health care professionals a concentrated opportunity to meet with representatives of specific pharmaceutical companies.

However, as the invitation sent to me and cited above suggests, there may be a growing downside to all of this. To comply with American Medical Association (AMA) guidelines regarding sponsored educational activities,[2] many pharmaceutical companies now hire independent third-party vendors to organize and host their scientific updates. These vendors represent the interests of their pharmaceutical-company clients to independent health care professionals and justify their decisions and actions by claiming that their policies are necessary to comply with AMA guidelines.

The AMA guidelines are designed to protect the public against unethical collusion between pharmaceutical companies and health care professionals. The third-party vendors serve the interests of the pharmaceutical companies, but who represents the interests of independent health care professionals? The invitation cited above suggests that such considerations may be merited. Growing trends in the pharmaceutical industry suggest that concern for the interests of health care professionals may not be a trivial issue.

AMA Guidelines

The AMA has issued reasonable and fair guidelines describing ethical interactions between health care providers and the pharmaceutical industry regarding continuing medical education (CME) interactions. As summarized in Table 1, the guidelines suggest that meetings sponsored by pharmaceutical companies should be true professional experiences, and not, by contrast, brief educational sessions to justify company-paid vacations for health care providers. Ethically and legally, the latter would be considered *inducements* by companies to providers. The AMA mandates that all

Table 1. Summary of AMA Guidelines for Industry-Provider Interactions in CME Programs

- Events should be primarily devoted to educational activities.
- Program content should be objective and scientifically acceptable.
- Funding for programs should be made from pharmaceutical companies through third-party vendors to providers.
- Sponsorships for honoraria to providers should be reasonable and consistent with meaningful services provided.
- Travel and lodging arrangements provided to participants should be reasonable for the circumstances.
- Providers should qualify for honoraria or travel and housing support only if they are engaged to provide meaningful services to the vendor organization.

such meetings and any payments to providers for travel expenses, lodging, upkeep, meals, or honoraria be handled by independent third-party vendors—not by the companies themselves.

According to the AMA guidelines, providers must have a valid and ethical professional and business relationship with a pharmaceutical company to qualify for sponsored participation in such a meeting. As noted above, any sponsoring funds should *not* be paid by the pharmaceutical company directly to the provider; rather, they should be processed by the third-party vendor. Sponsorship may include a *reasonable* honorarium and travel and lodging expenses. The compensation should reflect the reasonable value of the services delivered by the health care providers, and the services rendered should be *meaningful*. Services may include the presentation of educational programs, participation in the organization and maintenance of educational speakers bureaus, or consultation.

The AMA guidelines also address the content of these symposia, noting that the educational content should promote "objective scientific and educational discourse." The AMA suggests that independent committees should review the proposed content of these presentations before the program is held. The guidelines strongly imply that pharmaceutical companies should be separated from the details of the educational activities by their hired third-party vendors and their contracted academic organizers and presenters.

Relevance of AMA Guidelines to Diabetes Care

The increased competition among pharmaceutical products and the increasing numbers of drugs for the treatment of diabetes have intensified pharmaceutical companies' efforts to gain opportunities to present information in favor of their products. Therefore, meetings, such as third-company sponsored CMEs, have become more prevalent. In 1995, fewer than four companies sponsored such meetings; in the past year, more than 10 companies offered them.

In some instances, these meetings focused on areas of diabetes in which there are at least two similar, competing therapeutic or diagnostic products. For the companies, acquiring an audience of key providers for a defined period of time to whom arguments, subtle or not, in favor of the use of their specific product may be made, is a very provocative opportunity.

From a marketing perspective, these events are important to give relevant providers two sorts of key messages. The first type of message involves explaining relevant scientific principles that are essential to understanding how new agents or techniques work. Such information would be important, for example, in enhancing provider understanding of how a new class of antidiabetic agents, such as thiazolidinediones, works. The same would be true for new technology involving home blood glucose monitoring or new chemical formulations for insulin analogs. The process of enhancing provider knowledge about scientific information that is not product-specific and that has clear educational value is one positive aspect of these meetings.

The second type of message presents a set of more complicated and delicate questions. These messages impart information, often quite detailed, about product-specific features and distinctions among competing products in a given class. It is this type of message that is perhaps the most vulnerable to excesses. Third-party vendors, subject to review from their corporate clients, may make efforts to present such topics as objectively as possible. However, they know that, at the end of the day, their pharmaceutical clients will judge whether the meeting's content and presentation had the impact desired from the corporate perspective. That perspective has to include the impact on sales and marketing of the pharmaceutical client's product.

As the number of diabetes-related products proliferates, the potential for such excesses increases. Differences between competing products may appear small from an objective, scientific perspective, but they cannot be small from a sales and marketing perspective. Any health care provider who has ever listened to a pharmaceutical company representative's impassioned arguments in favor of one drug versus its competitor knows the scenario. Thus, critical, independent assessment of the content of third-party CME programs is always a positive planning component.

Potential for Abuse

As this system has evolved, at least three areas of potentially serious abuse have emerged, and each merits careful monitoring. The first relates to signs of proprietary bias in third-party CME programs. The second concerns the meaningfulness of the services requested of providers by vendors (and their client

companies). The third relates to the reasonableness of demands for travel arrangements the vendors make on health care providers in the name of adherence to the AMA guidelines.

No doubt, efforts to monitor and restrain programmatic abuses in this third-party CME vendor system will receive much support from health care professionals. All of us should comment negatively in program reviews to the third-party vendor and to representatives of the relevant pharmaceutical companies when we see excessive bias in favor of the corporate agenda instead of objective science and open discussion. Table 2 lists some of the clear evidences of bias seen at CME programs during the past few years. These include the taping and careful monitoring of discussions by vendors and by attending representatives of the sponsoring pharmaceutical companies. The presentation of unpublished and poorly substantiated data as cornerstones for key assertions by program speakers would be a second area of concern. So would negative observations by program faculty about published data that tend to support competing products.

One program characteristic that providers often dislike is vendors limiting participant queries of the faculty to written questions only. Because vendors can and do screen written questions, this format is much less desirable than open, spontaneous discussion. At least one major vendor for diabetes CMEs routinely insists on this format with the justification that there are too many participants in attendance to permit open discussion.

The second area of concern, which was emphasized in the aforementioned *Wall Street Journal* article,[1] relates to the meaningfulness of the work asked of participants in exchange for sponsorship to attend CME programs. Under the AMA guidelines, providers may not attend third-party CME events under vendor or corporate sponsorship unless they are engaged to provide clearly relevant services.

One form of service that is considered meaningful is participation on a speaker's bureau or panel of providers organized by vendors to speak at their clients' educational conferences and seminars. Members of such panels commonly receive sponsorship for attending CME programs at which they give presentations.

Another form of service, namely that of "consulting," attracts more skepticism as a justification for paying travel expenses and honoraria to health care providers. Questions have been raised for some of these programs about how serious the use of provider consultants is. My own experience is that the use of provider consultants varies widely in terms of meaningfulness. In some programs, provider consultants work diligently to shape scientific and programmatic approaches. In others, their involvement may be limited to commenting on the artistic attractiveness of three glossy medical journal advertisements for a diabetes-related product.

A third and growing area of concern involves how vendors treat providers in terms of travel and lodging arrangements for CME programs. The invitation cited at the beginning of this article is the most extreme and outrageous example of industry trends that I have seen to date. Given the growing prevalence of these types of demands, however, it may not remain the most extreme case for long.

There is no question that, in many instances, the vendors do not have a deep concern for the logistical problems of their guests. Their primary interest in booking travel has to be the budgetary concerns of their corporate clients. They invoke the AMA guidelines as justification for demanding that providers book their travel arrangements at least a month in advance. This allows them to book flights at the cheapest fare code and lowest class of air service available. In most instances, this means issuing providers travel plans under "U" and "L" class fares, which are nonrefundable and cannot be changed.

For many providers with busy professional practices, accepting such travel arrangements is both risky and unfeasible. Such tickets confer the financial risk for amending travel to the health care professional. If the demands of their professional work require a change in flight plans, providers with such tickets discover that they are worthless for exchange. The providers then have to purchase full-fare tickets at their own expense.

Vendors have also started to make difficult demands regarding the days of travel. Again under the justification of adhering to the AMA guidelines, vendors demand that providers follow travel schedules that minimize the number of nights they will require lodging. For example, vendors now require providers to book their return travel on the day a meeting concludes, regardless of the available departure times or providers' expected home arrival times. Providers who cannot leave late in the day because of fatigue or transportation schedules are often required to pay for their own hotel stay that evening.

One trip that I was offered last year illustrates how unreasonable these travel and lodging plans can be. I was invited to attend a two-day weekend meeting on diabetes in a city in far western Canada.

Table 2. Evidences of Possible Bias in Third-Party CME Events

- Lack of open and spontaneous questioning of faculty by participants
- Advocacy of the sponsor's products based on unpublished or poorly documented data
- Negative observations of studies that support the use of products competing with those of the sponsoring company
- Detailed identification (via videotaping or note-taking) by sponsor employees of participants who question information offered in presentations

I was to leave for this meeting from my home in the eastern United States after work on a Friday afternoon and arrive at my hotel in Canada at 1:00 a.m. Pacific time (4:00 a.m. Eastern). The meeting was to start 6 hours later. Although the location for this meeting was a major airport destination, the vendor demanded that I fly a commuter airline turboprop for 3.5 hours to get the lowest possible fare. This vendor also insisted that I leave the West Coast on Sunday on a 2:00 p.m. Pacific time commuter flight home, with planned arrival at my residence at 3:00 a.m. Monday morning. The vendor asserted that paying for me to stay overnight on Sunday and fly back at a more reasonable hour on Monday would be in violation of AMA guidelines.

Providers need to know that more functional arrangements for this Canadian trip or any other trip do *not* violate AMA guidelines. While enhanced travel arrangements, such as first-class airline tickets for domestic travel, could be considered inducements, the AMA never mandated that providers be treated to the worst possible travel arrangements, which tax their physical endurance beyond acceptable limits. The operative word in the AMA guidelines is "*reasonable.*" In both the guidelines and related commentaries, the clear implication is that companies should offer providers arrangements that are reasonable *for the providers,* not for the budgets of corporate sponsors.

Providers may wish to consider arrangements that allow for necessary changes to travel because of reasonable professional issues. Providers have a right to be housed in a manner that will allow for reasonable periods of rest and sleep during CME trips. The AMA guidelines do not obligate providers to accept undesirable flight schedules or itineraries or to travel on commuter aircraft if alternatives are available.

Summary

Through the years, we have maintained the attitude that attendance at industry-sponsored CME meetings is a privilege. In former years, when our current ethical standards did not apply, this may have been true. But in the current climate, attendance at such meetings is supposed to be work and, in fact, has become work. In many instances, the attendance of health care providers is at least as attractive to the meeting's corporate sponsor as it is to the providers themselves, because the event offers the sponsor the rare opportunity for undiluted access to the scientific ear of the provider.

Unfortunately, the mistaken notion that attendance is more of a benefit to providers than to sponsors has permitted the growth of three undesirable trends: emphasis on subjective, less substantiated advocacy of possible differences among competing products; meeting agendas that ask providers to provide meaningless and trivial services as justifications for industry sponsorship; and negative attitudes by industry members and the vendor organizations they employ toward the logistical needs of the providers they hope to attract to these meetings. Because the focus of regulation and monitoring by the AMA and other organizations has been to prevent the use of these meetings as inducements to providers, there are presently no systems in place to protect providers from these trends.

Diabetes care providers are therefore encouraged to view the educational content of these meetings, the involvement of health care professionals in them, and the logistical arrangements related to them with an appropriately critical eye. The professional expression of criticism by individual providers for improper or unacceptable behavior by vendor organizations is presently the only means we have of restraining these undesirable trends.

REFERENCES

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