

Clinicians' FORUM

From time to time, the editors of *Menopause Management* field interesting clinical questions and dilemmas. In this forum, our Editorial Advisory Board members, experts in a range of fields related to midlife women's health, tell readers how they handle these situations.

The viewpoints expressed in "Clinicians' Forum" are those of the contributors, and not necessarily those of *Menopause Management* or The North American Menopause Society (NAMS).

Question: Over the past several months, increasing attention has been paid to the involvement of pharmaceutical companies in providing educational forums at hospitals, clinical practices and academic centers through the provision of speakers from their speakers' bureaus, luncheon support and educational handouts. Many centers are now banning this practice. Do you think this activity has induced inappropriate bias in the practice behavior of the audience? Has valuable education been provided? How does your institution monitor this activity? What, in the future, would be the best way to provide regular and timely updates to clinicians in practice?

Answers:

I am reminded of the title of a Shakespeare play, "Much Ado About Nothing," when the debate regarding pharmaceutical support is raised and naysayers are quick to remark that any financial support from this source should be avoided under most circumstances. Has there really

been such a tremendous negative fallout from this type of support that these heated debates are warranted?

My argument against this stance of significantly limiting pharmaceutical support for education and research falls into two categories. First, Utopia, which is difficult to define and more difficult to achieve, does not exist in any aspect of human existence; there is, **therefore, no** system that is perfect. With or without pharmaceutical support for research and education, those medical professionals who are going to be unduly influenced by any source for self-advancement will be. People, in general, are not perfect; if we were, each of us would follow traffic signals and speed limits, which are very objective guidelines for decreasing the relative risk of a motor vehicle accident. Unfortunately, these guidelines are not universally met by all

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drivers because each of us is “unduly influenced” by running late and/or being detained by traffic jams. As well, obesity and tobacco use, the major contributors to morbidity and mortality in this country, have no connection to pharmaceutical support being given to healthcare providers.

My second reason for not seeing the need to change the current system is that it is not broken. There will always be outliers who do not follow the rules but, judging from the marked techno-

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—Gloria Bachmann, MD

logic, pharmacologic and surgical advances over the recent past, the system has been working quite well. Research and development continues to be strong, with the overall endpoint being the decline in morbidity and mortality in the US. The three major reasons for death in the US (heart disease, cancer and stroke) have decreased due to better prevention and intervention—interventions that can be linked to education and research provided, to a significant degree, to physicians by the pharmaceutical corporations. Life expectancy also continues to increase with the advances that have been realized, partly, through this modality of funding.

Having a specific opinion of support for continuation of this funding, I wanted to balance my comments with other professionals working at my institution. To this end, I reached out to two of my colleagues to get their opinions. Dr. Richard Scott, Director of the Reproductive Endocrinology and Infertility Division at the University of Medicine and Dentistry of New Jersey—Robert Wood Johnson Medical School (UMDNJ-RWJMS), noted that we ... “desper-

ately need the support of Pharma. It seems extremely unlikely that any of us are going to be ‘bought’ by the comments of a speaker whom we select and invite. Are there biased docs out there? Probably in every field, and certainly there are a few in Reproductive Endocrinology, but I simply would not allow them to come and speak at our university. Common sense is still the best way to manage these things. At a time of greatly reduced budgets, the financial hardships that appear to be descending on an already overloaded system, reductions in travel funds for continuing medical education (CME), and an overall lack of discretionary funds means that we need Pharma’s unrestricted educational grants more than ever. It might be argued that if you have docs with poor ethical standards, then they could be biased. Quite frankly, if we have docs with poor ethical standards, there is already a much more serious problem.”

Dr. Todd Rosen, the Maternal Fetal Medicine Division Director at UMDNJ-RWJMS, countered thusly: “While I respect Richard’s comments, I feel differently about this matter. I believe it is easy for even an ethical physician or researcher to be influenced by industry. Certainly we need pharmaceutical and industry dollars for research, but the greatest care must be taken, with supervision by institutional review boards and journal editorial boards, to ensure that accurate data are being disseminated to healthcare workers and the public. Otherwise, we will repeat mistakes of the past. The lessons we have learned from the Merck Vioxx debacle and from other now-discredited work must be remembered. When dollars can directly influence our clinical care, we must be even more careful. *The New York Times* has detailed how the prescribing practices of oncologists have been heavily influenced by their reimbursements from drug makers. I have sat on P&T committees and have listened while physicians on staff, who are paid to get a drug placed on formulary, misrepresent the data. As a paid



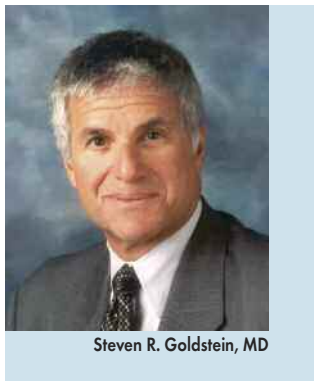
Gloria Bachmann, MD

speaker for industry, I have felt pressure at times to change my talk so a company's product is seen in the best light. I guess I would vote that with proper safeguards, dollars from industry for research are acceptable. I would like to hear both sides argue about whether we should allow industry to pay for speakers, etc, before making a final decision on this issue. However, while I would hate to give up these dollars myself, I feel that we would be best off with less of these types of activities."

Taking all aspects of the argument into consideration, my major concern becomes the obvious. If we take the extreme viewpoint and label this source of financial support for research and education as not acceptable except under extremely limited circumstances, I believe that there will be a significant halt in the medical progress we have seen in our lifetime.

—Gloria Bachmann, MD

This question raises several issues worth discussing. My institution does not seem to have a uniform policy on this. In our faculty practice



Steven R. Goldstein, MD

area there are still occasional lunches, as well as a "sample" closet that is intermittently stocked. I do not attend the lunches (I'm watching my weight and like to choose my own food). I prescribe medications based on patient need and sometimes go the closet but have not "changed my mind" if one product is not

there but another is. I *could*, however, see how that would be tempting to some physicians, especially if their patient population was in more dire financial straits than most of mine.

These activities are, however, very different than providing educational support in a CME fashion. This is where partnership with industry is relevant and valuable to all. Unrestricted educational grants, whereby the company giving the grant has absolutely no say in the programming (topic, speaker, slides, etc), is increasingly one of

the only ways to maintain a high-quality CME weekly program series. Top speakers require a modest honorarium and expense reimbursement. The practice of using unrestricted grants with a total firewall from grantor to program is an excellent use of industry goodwill and medical "community service." Increasingly, nonprofit institutions like my medical center cannot afford to fund such educational activities out of operations. Unfortunately, the perception of the public (and Senator Grassley) seems to be unable to distinguish between free food, pens and other "favors" and a truly unrestricted, unencumbered educational grant.

Finally, of all the societies with which I have ever been involved, NAMS is clearly the most honest and transparent. In the future, unless the government or private foundations want to step up to the plate and fund such important educational activities, allowing industry to be involved but kept at arm's length is, in my opinion, a reasonable and workable format.

—Steven R. Goldstein, MD

The overwhelming majority of physicians are careful in their judgment, critical and objective, and I am a firm believer in the faith of good medical practice. To think that a lunch or dinner provided by pharmaceutical companies skews the judgment of highly trained and well-meaning physicians is naive and biased. In the vast majority of the educational CME and non-CME programs the educational value is high, especially when speakers are allowed to speak freely and answer questions in a scientific manner (on- or off-label). Physicians are listening for the "commercial message" in a so-called "promotional" talk; once they hear that message their listening is over, and the speaker has lost their respect. Physicians want to learn about the published data but also want to have answered their many questions concerning pa-



Paul D. Miller, MD

tient management in situations in which patients do not “fit” into the randomization criteria (ie, real-world practice).

Our institution allows only CME activity but restricts pharmaceutical sales and scientific personnel in terms of access and providing “box lunches,” resulting in far fewer students and house staff attending CME conferences (they need to eat and have very limited time and finances). The “trade-off” is fundamentally less overall education.

The regulators need to allow “freedom of speech.” Have nationally recognized, highly regarded speakers dive **into** the “promotional” talks as they see fit—using any slides they choose and answering any questions that may be asked. Education can be successful only if it is open and not monitored. Bad speakers and “hired guns” won’t last long. Physicians are too smart and cautious to be influenced.

—Paul D. Miller, MD

In moves reminiscent of the Taft-Hartley Act¹ it has recently become fashionable to expunge any relationships between the pharmaceutical and devices industries and the medical professionals they address. The seeds for these actions arise from abuses on both sides that have been considered to be sufficiently egregious or corrosive to outlaw educational and investigative relations between the parties.

While there have undoubtedly been abuses of trust and improper use of leverage, there are many examples of fruitful interactions in education, improved practice and innovation that resulted from appropriate uses of

industry resources in support of educational, clinical and research programs. Thus, in these times of maximal pressure on educational resources, clinicians’ time and support for scientific inquiry, it behooves those in positions to do so to avoid such broad prohibitions in favor

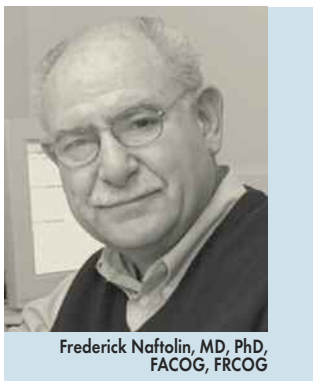
of development of rules that are both mutually rewarding and enforceable. While good fences *do* make good neighbors, walls often result in untenable separations. While “not tossing out the baby with the bath water” seems trite, it does apply **here**. Just as it was necessary to revisit the over-reactive aspects of the Taft-Hartley Act, it seems that we need to go back to the drawing board on the severity and application of prohibitions on interactions between medicine and industry.

—Frederick Naftolin, MD, PhD, FACOG, FRCOG

Reference

1. Federal Labor-Management Relations Act, 80 Pub.L. 101;61 Stat., 1947.

My personal experience with industry-based symposia has generally been favorable. The oversight by the FDA is appropriate since a uniform surveillance of ethical principles and of transparency of “potential conflicts of interest” is necessary. I do, however, feel that the enforcement is inappropriately applied at times. Locally, we have a very restricted policy regarding pharmaceutical-sponsored CME: none is allowed. Although this is valid, it does make it difficult to finance a good variety of speakers. Also, it drives most of the industry-sponsored speaking either to providers’ offices or to dinner meetings; these are harder to monitor. Finally, **Pharma** personnel can monitor individual provider prescription preferences, which I feel gives them a greater advantage to bias their information when they already know the providers’ practice patterns. Therefore, I am more in favor of **Pharma**-sponsored events at national meetings, hospital-based grand rounds and regional symposia with appropriate restrictions in place. I have never felt that discussions were biased in such forums because of the mode of sponsor-



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ship, since they were and are managed by the administrative body running the meeting (society or hospital-based CME committee). Also, when the audience is not preselected (as they are in dinner meetings) a more open forum for discussion can occur.

—*Veronica A. Ravnikar, MD*

Bibliography

Massachusetts Department of Health and Human Services. Pharmaceutical and Medical Device Manufacturers' Code of Conduct. 2009:July 1. Available at: www.mass.gov/dph/pharmamed.

PhRMA recently updated its “Code on Interactions with Healthcare Professionals,”¹ making several changes designed to enhance the independence of CME. The PhRMA Code states that funding for CME should support a full range of treatment options and not promote a particular product; companies should separate CME grant-making decisions from sales and marketing departments, and companies should follow CME accreditation standards and respect the independent judgment of CME providers.

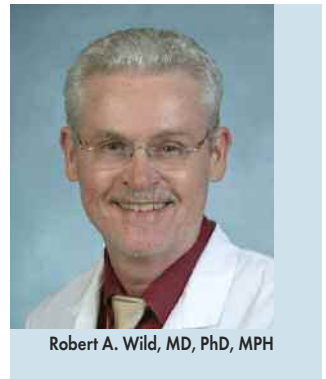
In my view, the recent changes in the way Pharma interacts with physicians subsequent to the task force report issued by the Association of American Medical Colleges² has both helped and hindered the educational process. In our institution, extramural support for CME has diminished dramatically. This has necessitated greater reliance on in-house faculty and resident initiative to meet the never-ending need to keep up to date, and has resulted in a loss of outside viewpoints and information. Our journal club is no longer held in faculty homes, where Pharma-sponsored events assured palate satisfaction and fed the hungry mind. Instead, we are incorporating journal club into the regular daytime departmental activities and regularly scheduled educational events. Gone are the sponsors who offer a cup of cappuccino to help make the experience tantalizing. The mood is certainly less festive and the attendance may well be down. Is this, overall, a good thing? Is it a bad thing?

Historically, we have witnessed clear examples of salespersons trying to influence prescribing

practices with biased information. This has been dramatically reduced. That’s a good thing. Unfortunately, we have also witnessed outstanding national organizations struggle for funding in an environment in which incentive for Pharma to support activities becomes diminished and the educational efforts subsequently suffer. This threatens quality. In my view, we cannot stay on the cutting edge without the assistance of one of the world’s most precious resources: access to intellect, development and creativity. America’s pharmaceutical research companies are committed to advancing the science of medicine and helping patients in need. Pharmaceutical researchers work tirelessly to better understand the biology of disease and translate this knowledge into the development of new life-saving and life-enhancing medicines—medicines that provide hope to millions of patients around the world. Academic medical centers are vital partners in this enterprise.

Just as the process of drug development is complicated, so too are the resulting medicines and their proper use. Effective, responsible marketing by pharmaceutical research companies plays a critical role in fostering the appropriate use of medicines.

Providing physicians (and medical students) with timely, accurate information about the medicines they prescribe clearly benefits patients and advances health care throughout the US. Meetings with technically trained pharmaceutical research company representatives, some of whom are healthcare professionals themselves, help inform physicians about a wide range of topics related to prescription medicines, such as new treatment options, appropriate dosing, emerging safety developments and potential interactions with other drugs. Importantly, pharmaceutical research companies must be careful (and many are) to ensure that their relationships with both healthcare professionals and students are ethical and appropriate. Physicians who are involved in CME and who sit on



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committees that draft guidelines explaining best practices are often leaders in their fields. In many cases, they also are the individuals involved in clinical trials of new medications or expanded indications for existing medicines, and are on the cutting edge of the research.

Existing federal law is very clear: pharmaceutical research companies must make sure the information they convey to physicians is accurate and consistent with pharmaceutical product labeling approved by the FDA. These activities are monitored by the FDA, which turns any evidence of impropriety over to the Department of Justice for in-

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—Robert A. Wild, MD, PhD, MPH

vestigation. What's more, the companies and their representatives must not give physicians anything of value to induce prescribing or in exchange for prescriptions written by the doctors. Pharmaceutical research companies must comply with strict anti-kickback laws and other criminal and civil provisions enforced by the Justice Department.

In addition, pharmaceutical companies have adopted self-imposed guidelines on marketing activities. PhRMA's Code on Interactions with Healthcare Professionals¹ provides guidance on how sales personnel can and should maintain ethical relationships in their discussions with healthcare professionals. The Code states that all forms of entertainment are inappropriate. The guidelines also state that only modest meals should be allowed and any items provided should be primarily for the benefit of patients and should not exceed \$100 in value.

In the end, interactions between pharmaceutical sales representatives and healthcare professionals, including those who work and train in academic medical centers, enhance public health and improve patient care. Pharmaceutical research companies must take this responsibility seriously and remain committed to ensuring that these in-

teractions adhere to the highest ethical standards.

CME is just one source of information helpful to physicians. Healthcare practitioners gain important knowledge from journal articles and practice guidelines, and from speaking with peers. The traditional CME model is being replaced by workshop formats, with physicians in training being taught how to evaluate evidence and access electronic information in keeping with the information technology explosion. This will strengthen the need for professional organizations to ensure education access and quality.

Like academic medical centers and regional hospitals, which also fund educational programs for physicians, PhRMA member companies believe they should contribute to the process by which physicians remain current on the most effective treatment options. Restricting industry funding of the very activities that improve public health and protect patient safety is not in the best interest of public health or our patients. Highly educated physicians who are leaders in their fields have the experience and integrity to make medical recommendations based on their best medical judgment. Still, to safeguard against even the perception of a conflict of interest, medical societies and others already have drafted robust codes of conduct.

There is no evidence that a company's funding of CME or other physician educational activities, when provided within appropriate guidelines, creates bias. We need to constantly evaluate this issue and monitor to see if bias is occurring. I applaud sincere efforts and commitment by Pharma to help develop high-level standards. Pharma's support of professional organizations and generic support at the local level is crucial to our ability to stay competitive. As the pendulum swings, so too can over-regulation be accompanied by absurd over-kill that results in the baby being "thrown out with the bath water."

—Robert A. Wild, MD, PhD, MPH

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2. Association of American Medical Colleges. Report of the Task Force on Industry Funding of Medical Education. Washington, DC: 2008. Available at: www.aamc.org/research/coi/start.htm (Accessed July 25, 2009.)

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