

Guidelines Zap Pharma Freebies; Modest Meals OK

BY MARY ELLEN SCHNEIDER

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The free pens and mugs adorned with the names of commonly prescribed drugs are soon to be a thing of the past, thanks to a new set of voluntary guidelines from the Pharmaceutical Research and Manufacturers of America.

But the real impact of the voluntary guidelines is still up for debate.

The guidelines, which will go into effect in January, were released this summer as pressure mounted from Congress and the academic medical community for industry to rein in its marketing practices. They update the 2002 PhRMA Code on Interactions with Healthcare Professionals.

"Although our member companies have long been committed to responsible marketing of the life-enhancing and life-saving medicines they develop, we have heard the voices of policy makers, health care professionals, and others telling us we can do better," Billy Tauzin, PhRMA president and CEO, said in a statement.

Among the changes outlined in the new guidelines is a prohibition on even "modest" gifts to physicians if they lack educational value. For example, the ubiquitous pens and mugs given out by pharmaceutical representatives are no longer acceptable under the new code of conduct. However, gifts valued at \$100 or less that are used primarily for patient or health care professional education, such as an anatomical model, are still allowed on an occasional basis.

The guidelines also prohibit sales representatives and their immediate managers from taking physicians out for dinner, even if they have an educational presentation to make. However, they can still provide "modest" meals,

such as pizza, in the office or at the hospital if they stay to provide their educational session there. The voluntary guidelines also prohibit companies from providing any type of entertainment or recreational items such as tickets, sports equipment, or trips, even if the item is inexpensive.

In terms of continuing medical education (CME), the guidelines call on pharmaceutical companies to separate their CME grant-making functions from their sales and marketing activities. Subsidies to attend CME meetings should not be given directly to physicians, according to the guidelines. Instead, any funds should be given directly to the CME provider, who can use the money to reduce fees for all attendees. Companies are also not allowed to provide meals directly at CME events.

The guidelines continue to allow pharmaceutical companies to provide scholarships to medical students and others in training so they can attend educational conferences, as long as the recipients are chosen by the academic or training institution. The guidelines also call for greater transparency among physicians who work as industry consultants. Physicians who serve as company consultants or speakers and also serve on committees that set formularies or clinical practice guidelines should disclose their industry relationships, according to the PhRMA guidelines.

The changes were praised by some in the medical community as progress on the part of the pharmaceutical industry to respond to criticisms and police itself.

"It's a big step forward," said Dr. David Korn, chief scientific officer for the Association of American Medical Colleges (AAMC), which recently released its own report on industry funding of medical education. Although the guidelines don't go as far as some academic medical institution policies, they are significant because they appear

to have the full backing of the industry, he said.

In the AAMC report, released in June, the organization calls on medical schools and teaching hospitals to prohibit the acceptance of any gifts from industry. It also instructs academic medical institutions to set up a central CME office to coordinate the distribution of industry funds and strongly discourages participation by faculty in industry-sponsored speakers bureaus.

But others criticized PhRMA for leaving loopholes that allow for much of their marketing activities to continue.

The first major loophole is that the policy is voluntary, said Dr. Carey Chisholm, residency program director for emergency medicine and professor of emergency medicine at Indiana University, Indianapolis. It also continues to allow for a significant amount of marketing through the "modest" on-campus meals and through off-campus meals with industry consultants, he said.

Dr. Daniel Carlat of the psychiatry department at Tufts University, Boston, labeled the changes "primarily cosmetic." PhRMA appears to be decreasing marketing activities, he said, but they are keeping the tactics that are most successful. In addition, although the code prohibits sales representatives and their immediate supervisors from taking physicians out for dinner, there are no restrictions on dinners with pharmaceutical company consultants, said Dr. Carlat.

Dr. Howard Brody, director of the Institute for the Medical Humanities at the University of Texas Medical Branch in Galveston, said ultimately, the medical profession needs to make these changes. Physicians should think about how they can learn about new treatments without meeting with sales representatives, forego samples, and say no to free lunches provided by pharmaceutical companies, he said. ■

Physicians Educate Congress on Realities of CME Funding

BY ALICIA AULT

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WASHINGTON — Without pharmaceutical industry funding, continuing medical education is in danger of faltering, panelists emphasized at a forum aimed at educating Capitol Hill staffers on CME funding.

The forum, sponsored by the Center for Medicine in the Public Interest, a New York-based nonprofit organization, and the Coalition for Healthcare Communication, an umbrella group for advertising agencies and medical journal publishers, was called in response to efforts from senators, House members, and accrediting organizations for greater accountability for CME funding.

In July, a task force of the Association of American Medical Colleges said that academic medical centers should discourage faculty participation in industry-sponsored speakers bureaus. A month earlier, the Accreditation Council for Continuing Medical Education proposed tightening restrictions on commercial support of CME, and possibly even banning industry funding.

But the panelists, who included a group of CME providers, several physicians, and a medical journal editor, warned that withdrawing such funding would undermine a well-run and much-liked enterprise.

"CME in the U.S. is a great success story," said Dr. George Lundberg, a former editor of JAMA and currently editor-in-chief at Medscape.

It changes knowledge, skills, and patient

outcomes, he said, adding that surveys have shown that physicians are in favor of industry support.

Dr. Michael Weber, a professor of medicine at the State University of New York, Brooklyn, said that he views pharmaceutical company funding of CME as a mandate, "not a luxury." Manufacturers have a responsibility to educate providers on how to use their products, he said.

The pressure for transparency is leading to what Dr. Weber called censorship. He said he has had to alter presentations at the request of meeting leaders in the United States, whereas a recent presentation at the European Society of Cardiology was completely within his control.

Dr. Jack Lewin, CEO of the American College of Cardiology, said he had "serious, serious concerns about the recent attacks" on CME.

The ACC has multiple steps to remove conflicts of interest from its professional and educational programs, he said, adding that in addition, it discloses its industry funding on its Web site.

Dr. Lewin said that there had been abuses in the CME arena, but that the move to clamp down on those bad actors had professional societies and pharmaceutical companies running for cover.

There is evidence to support his claim. Public Citizen's Health Research Group, in comments sent in September to the ACCME on its proposal to limit or ban industry support of continuing medical education, said that, "Despite a quadrupling of commercial support for CME over the past 10 years, in 2007, the percentage of

CME income provided by commercial interests actually decreased to 2002 levels."

Public Citizen advocates an end to commercially funded CME. Because CME is a condition of licensure, demand will re-

main, according to the group. "Shifting the burden of funding toward physicians (not exactly a group occupying the lower rungs of the earning ladder) would attenuate the effect of lost revenue." ■

Drugmakers Set to Disclose Payments

Two pharmaceutical companies will begin publicly disclosing how much each pays physicians.

Eli Lilly & Co. was the first company to step forward, followed a day later by Merck & Co.

Lilly is starting a registry that will compile payments to physicians who have served as speakers or advisers for the company. It will be available to the public on the company's Web site as early as the second half of 2009, Lilly officials said in a statement. The registry will be updated each year to reflect the previous year's payments.

The company said that by 2011, it aims to report whatever is required under the proposed Physician Payments Sunshine Act. That bill (S. 2029) was introduced by Sen. Chuck Grassley (R-Iowa) and Sen. Herb Kohl (D-Wis.) in November 2007. As currently written, it would require manufacturers of pharmaceuticals, medical devices, and biologics to disclose the amount of money they give to doctors through payments, gifts, honoraria, and travel. Product samples for patients would be excluded.

The bill was endorsed by several major drug companies, including Lilly and Merck, by the Pharmaceutical Research and Manufacturers of America, the Advanced Medical Technology Association, and by the Association of American Medical Colleges, among others. But it has not had any movement since its introduction.

In a statement, Sen. Kohl congratulated Lilly, saying the company was "fulfilling the obligations of the Physician Payments Sunshine Act before it has been enacted."

Merck said that beginning this month, it will disclose the grants to patient organizations, professional societies, and others for "independent professional education initiatives," which would include continuing medical education. Next year, it will include other grants made by the Merck Company Foundation and the Merck Office of Corporate Contributions. The information will be posted on its Web site.

Beginning in 2009, the company will also start disclosing payments to physicians on its speakers bureau.