

CME BRIEFING

NEWS, OPINIONS, AND PERSPECTIVES IN CONTINUING MEDICAL EDUCATION ~ SPRING 1998

A Service of Professional Postgraduate Services®, a division of Physicians World Communications Group

FDA Issues New Guidance for Industry-Supported CME

After six years of revision and amendment, the FDA unveiled its final guidance for industry-supported continuing medical education this winter. The 7-page document, "Guidance for Industry," describes how the pharmaceutical industry can continue to support CME without running afoul of the FDA. (See the boxed insert on page 4 for a summary of the main points of the guidance.)

As the document is disseminated throughout the CME community, providers are evaluating ways in which the guidance may affect the way they conduct their operations. "Understanding the guidance is important for providers," says Richard F. Tischler, Jr, PhD, a former

ACCME staff member and director of continuing medical education, who is currently president of RF Tischler Jr. & Associates, Inc.

"From the perspective of a CME provider, these are the rules that our commercial supporters have to live under. I think in being good partners in the CME enterprise we have to be sensitive," Dr Tischler says, "and work with the commercial supporters in trying to understand and implement them."

FDA Concerns Regarding CME

While the FDA has no direct authority over CME providers, its mandate does include regulation of pharmaceutical labeling and advertising—and, by extension, any drug company

activity that the agency perceives as promotional. The key is in the appearance and the classification of programs.

"What we are looking for is the difference between scientific and educational programs versus promotional programs," according to Ilissa Bernstein, Senior Science Policy Advisor for the FDA. "The new document sets forth guidance for how the industry can support continuing education programs without being subject to regulation," says Ms Bernstein.

The main point the FDA considers in evaluating industry-supported educational programs is whether the program has been developed independently. Educational activities that do not meet the agency's criteria for independence would be subject to the same regulatory scrutiny as phar-

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ANSWERED IN THIS ISSUE

How does the final FDA guidance to industry affect CME providers?



*Faculty honoraria:
Who pays?*



Who Pays the Speaker?

In order to maintain educational independence in CME, the ACCME Standards for Commercial Support clearly state that industry support of a particular CME program must be provided in the form of a grant or other "no strings attached" payment. The CME provider is then responsible for paying both the speakers' honoraria and any expenses.

Nevertheless, some providers and industry leaders say they have noticed a trend—particularly among smaller, state-accredited institu-

tions—in which companies will pay speakers directly for a CME presentation. For example, Ted Warren, PhD, Education Coordinator for the Kansas Medical Education Foundation (based in Topeka), says that in one week, he recently turned down two of eight proposed contracts because presenters either solicited, or companies wanted, direct payment for speakers.

Rules Are Being Skirted

The language of the ACCME stan-

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CME BRIEFING

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The mission of this newsletter is to disseminate news and information about CME and to foster dialogue among the concerned parties, including the medical profession, government, industry, and CME sponsors.

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We are proud of our 25-year history of medical publishing, and feel a responsibility to enhance medical education by improving communication among interested parties. Our proactive relationship with the government, the medical profession, industry, and CME sponsors will benefit from the input of our readers.

Please address your comments or questions about this newsletter to CME BRIEFING Editor, Professional Postgraduate Services® Division, Physicians World Communications Group, PO Box 1505, Secaucus, NJ 07096-1505.

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FDA Issues New Guidance

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maceutical advertising and promotion, which must adhere strictly to the FDA-approved product information (as published in the *Physicians Desk Reference*®). Ms Bernstein emphasizes that "Each of the points described in the guidance is important, but no single factor would be used to determine independence."

Impact on CME Providers

Rafael C. Sanchez, MD, Medical Director for the Network for Continuing Medical Education, believes that the new guidance is an improvement over the old draft guidelines which the Agency first issued in 1991 and then revised in 1992. "What impresses me about the new guidance is that it's a little bit better focused and it's not as verbose, although it speaks to the same issues that the original draft document did," says Dr Sanchez.

Because ACCME standards are generally more strict than the new FDA guidance, most CME providers do not foresee any major change in how they conduct their programs. Dr Sanchez observes, "I look at the ACCME standards, and I look at the guidance, and I don't see anything in either that is difficult to comply with if you have a sense of responsibility."

Marc DesLauriers, PhD, Director of Education at the Menninger Clinic in Topeka, Kansas, agrees. In the new guidance, he says, "There is more personal discretion allowed. They really support using professional judgment and that encourages flexibility in meeting the standards."

Differences from Earlier Guidelines

In the process of developing the final guidance, the FDA asked for industry and provider comments on the original draft, and made its revi-

sions accordingly. The agency detailed its decision-making process in a notice published in the December 3, 1997 issue of the Federal Register. (See the boxed insert on page 5 for an overview of differences between the final FDA guidance and the ACCME standards.)

Among the most striking differences between the original draft and the final guidance is the elimination of "obligate pathway" wording regarding promotional materials. Under the draft guidelines, no promotional material was allowed in any place an audience member would be forced to pass while attending a presentation. That requirement has been replaced with a simple ban on marketing in the room of the presentation—a position which echoes the ACCME standards.

Because ACCME standards are generally more strict than the new FDA guidance, most CME providers do not foresee any major change in how they conduct their programs.

Also gone from the final guidance is a requirement of written agreement between CME providers and commercial supporters. While the guidance emphasizes the value of a written agreement for documenting independence, it is no longer mandatory. "We do say that it is one way that the provider and the company could document steps that they take to insure that the program is independent," says Ms Bernstein, "but we're not just looking at a written agreement."

Another significant difference centers on the issue of disclosure.

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View From Industry

While the FDA's new guidance has an immediate effect on CME providers, the agency's most direct influence, of course, is on pharmaceutical companies and the advertising and labeling of their products. Industry officials, therefore, also wonder what the new guidelines might mean for their partnership with CME providers.

Frederic S. Wilson, Manager of Professional Education for Procter

“The reason the FDA made the guidance less prescriptive was that they wanted to allow some flexibility for both CME providers and industry. At the same time, the regulators made it clear they were not deferring their responsibility to an organization like ACCME and that they were still going to actively monitor industry's role in continuing medical education.”

—Frederic S. Wilson,
Procter and Gamble Healthcare

and Gamble Healthcare, notes that this issue was discussed at a recent meeting of the National Task Force on CME Provider/Industry Collaboration. “One of the things we were concerned with was the potential for closer regulatory scrutiny,” he says.

“As we talked it through, it became clear the reason the FDA made the guidance less prescriptive was that they wanted to allow some flexibility for both CME providers and industry,” according to

Mr Wilson. “At the same time, the regulators made it clear they were not deferring their responsibility to an organization like ACCME and that they were still going to actively monitor industry's role in continuing medical education.”

The new guidance recognizes the “important role” of accredited institutions but does not give any specifics as to how it will work with those institutions. At the meeting, industry leaders were assured that “as long as they continued as they have been, supporting CME using the draft policy guidelines, they will certainly be in compliance with the final guidance,” according to Mr Wilson. He does not envision any change in the way Procter and Gamble supports CME programs based on the new document.

Will Scrutiny Be Relaxed?

J. Brian O'Toole, PhD, of Boron Lepore and Associates, believes that industry already takes a more cautious approach than the guidance might suggest, and will continue to do so. “I've not seen any relaxation of standards,” he says. “The legal counsel in a number of pharmaceutical houses I've been working with have taken a much more conservative approach than what the guidance would allow. I also think there are a number of accredited providers who have taken an internal stance that's more conservative and less risky than what the guidance has allowed. That's just a matter of how we function.”

While the 1992 draft policy may have taken the industry by storm, says Dr O'Toole, he predicts the new guidance will have less of an impact on day-to-day operations. “The industry has come a long way in understanding and implementing the policies,” he said. “When the first

guidance came out, there was some ignorance on the part of industry—and, I think, to a certain extent on the part of providers, too. But we've both learned a lot since then.”

As a result, Dr O'Toole says the guidance doesn't seem as revolutionary as it did a few years ago. “When the FDA first came out with the guidance, it was major news, but I don't know if they've taken hold a second time around. My guess is that industry will probably continue its current stance; it's worked for them up to this point.”

Defining Independence

But Brian Russell, President of CoMed Communications, expressed concern about the new guidance's potential effect on industry's willingness to support continuing medical education. “I think that this document very clearly shows that the FDA will be evaluating intent,” he says. “And I think that's valid. I think that providers have always believed

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—J. Brian O'Toole, PhD,
Boron Lepore and Associates

in that and have acted with the best of intent.”

At the same time, Mr Russell worries about the ambiguity surrounding certain questions of direct or indirect influence of a company on a provider. “The guidance dis-

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FDA Issues New Guidance

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While the original draft policy statement stated that providers should disclose whether a particular CME presenter was suggested by the company, the final guidance indicates that a general disclosure of any financial relationship between presenters and the supporting company is sufficient.

In addition, the final guidance does not require presenters to disclose off-label or unapproved uses of a product in each part of the presentation in which they are men-

Among the most striking differences between the original draft and the final guidance is the elimination of “obligate pathway” wording regarding promotional materials.

tioned. Rather, the agency asks that there be an “up-front” general disclosure if off-label or unapproved uses will be discussed during the CME activity.

Impetus for FDA Involvement in CME

In 1991, then-FDA commissioner David Kessler, MD, published a letter in *The New England Journal of Medicine* detailing agency concern over the independence of continuing medical education and pharmaceutical research. Citing the enormous increase in the amount of money spent on symposia funded by pharmaceutical firms, Dr Kessler expressed the need for greater vigilance in the industry.

Dr Kessler also wrote in his letter that, in the past, the agency had

Highlights of FDA’s Final Guidance for Industry*

In its final guidance, the FDA states that it will consider the following factors in evaluating CME activities and determining their independence from industry.

1. The CME provider maintains full control over program content and planning, including selection of speakers and moderators.
2. There is meaningful disclosure to the audience of: a) company funding; b) significant relationships between provider, presenters, or moderators and the supporting company; and c) whether any unapproved uses of products will be discussed.
3. The intent of the supporting company and the provider is to produce an independent and nonpromotional activity focused on educational content and free from commercial influence or bias.
4. There are no legal, business, or other relationships between the supporting company and the provider that might allow the company to exert influence over the content of the activity.
5. Individuals employed by the CME provider are not also involved in advertising, sales, or marketing activities for the supporting company.
6. The provider does not have a history of producing activities that fail to meet objective standards.
7. Whether multiple presentations of the same program are being held. (The guidance adds a footnote, however, recognizing the importance of some repeat programs.)
8. The audience is not selected by the sales and marketing department of the supporting company.
9. There is an opportunity for meaningful discussion or questioning during live presentations.
10. Information about the supporting company’s product is not disseminated after the program except in response to an unsolicited request.
11. Promotional activities do not take place in the meeting room.
12. There are no complaints by the provider, presenters, or attendees regarding attempts by the supporting company to influence content.

** Although the FDA does not require strict adherence to each one of these factors for every CME activity, the guidance stresses that the agency will be looking for patterns of compliance with these factors. Furthermore, the guidance states that these factors are not exhaustive and other factors may be considered in a particular case.*

tried to minimize a “chilling effect” on free exchange of scientific information by warning commercial supporters rather than threatening action against physicians who participated in those activities. Now, he warned, the agency was ready to hold individual physicians accountable. “The FDA will no longer exercise this regulatory restraint across the board,” he wrote.

J. Brian O’Toole, PhD, of Boron Lepore and Associates, believes that since then, the industry has largely reformed itself. “I think the FDA acted in response to political pressures; I think it was also in response to what was happening in the industry at that time. There were a number of practices that some members of the profession thought were unacceptable.”

At the same time, Dr O’Toole notes that many people considered the FDA’s initial approach to regulation of CME somewhat high-handed. “To a certain extent, they said, ‘You will do it this way’ rather than, ‘What

Unlike the ACCME Standards, which give specific required steps for an accredited organization to develop an independent program, the FDA guidance is much less prescriptive and is designed to show how the Agency might evaluate intent.

do you think about this?’ or ‘How might we do this better?’ ”

Dr O’Toole thinks that stronger enforcement of standards by the ACCME and other accrediting organizations explains some of the flexibility in the new guidance. “The ACCME Standards for Commercial

Support do, in fact, embrace what the FDA was demanding—and they do it in a way that makes sense. And

This document details the process the FDA went through in coming up with its new guidelines,

Key Differences in Final FDA Guidance and ACCME Standards

- **Obligate pathway**

The final guidance does not require that promotional material is removed from any place a program attendee would be forced to see it. Instead, it states only that the agency will consider whether there are promotional activities, such as presentations by sales representatives or promotional exhibits, taking place in the meeting room.

- **Written agreement**

The FDA guidance does not demand a written agreement between supporter and provider as required by ACCME; the FDA does, however, suggest that an agreement is a good way to document program independence.

- **Disclosures**

- **Affiliation of presenters:** The agency no longer requires that providers disclose whether a CME presenter was suggested by the company; instead, it indicates that a general disclosure of all financial relationships between presenters and the supporting company is sufficient.
- **Off-label or unapproved uses:** The agency asks that there be a general “up-front” disclosure statement if off-label or unapproved uses will be discussed during the CME activity.

also, in a way that I think most people can live with.”

Focus on Intent

Unlike the ACCME Standards, which give specific required steps for an accredited organization to develop an independent program, the FDA guidance is much less prescriptive and is designed to show how the Agency might evaluate intent. Deborah Teplow, PhD, Vice President for Strategic Planning for Projects in Knowledge, Inc., says, “The key to understanding the FDA’s thinking on the issue of CME independence is in the Notice, published in the Federal Register on December 3.”

including the comments it received and its concerns about free speech issues. “I don’t think you can appreciate the subtleties and the nuances that are embedded in the guidelines without reading the Notice,” she says. “The Notice, we found, is particularly helpful—if not essential—for understanding and interpreting the final guidance, and for being able to implement it effectively.”

Understanding how the FDA thinks about CME, says Dr Teplow, is important for regulators, industry and providers alike. “Ultimately,” she says, “we’re all in the same boat, and the overall goal for all of us is to better educate physicians and to improve patient care.” ~

Who Pays the Speaker?

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dards is unambiguous on this point. Section 5(a) states, "Funds from a commercial source should be in the form of an educational grant made payable to the accredited sponsor for the support of programming... No other funds from a commercial source shall be paid to the director of the activity, faculty, or others involved with the supported activity." Providers who act otherwise risk losing ACCME accreditation.

Richard F. Tischler Jr, PhD, a CME consultant and former ACCME staff member, says he thinks the organization's position is straightforward. "It's fairly clear, and it was clarified in subsequent statements by the ACCME in its newsletter that the faculty should receive their payment from the accredited sponsor." Dr Warren acknowledges that most

Particularly for smaller providers with a more limited budget, the temptation to bypass the paperwork involved in processing a grant may be great.

commercial companies are scrupulous, he says, but he does get calls from those who offer to "take care of everything" in regard to speakers at a CME program.

When Dr Warren says he doesn't work that way, the companies will occasionally act surprised. "They say things like, 'you are kind of a minority. In little places the providers usually like us to do everything.' Well, if that's a common approach to a 'lit-

tle place'—and Topeka, after all, is the state capital—that tells me something about how many places around the country are, in fact, letting the companies pay the speakers directly."

Payments Are Administrative Burden

Particularly for smaller providers with a more limited budget, the temptation to bypass the paperwork involved in processing a grant may be great. But Dr Warren believes a supposed lack of administrative resources is a weak excuse. "I have spoken to providers about this. And I say if you don't have the administrative staff to be able to take in money and then write a check, then what other things are you not able to do?"

In some institutions, CME operates on a shoestring. "I have sympathy for the CME directors in the smaller hospitals; they tend not to get a tremendous amount of support," said Dr Tischler. "But if they're going to be an accredited sponsor, part of their requirement, at least according to ACCME's Essential #6, is that there be sufficient resources." (Essential #6 reads: "The sponsor shall provide evidence that management procedures and other necessary resources are available and effectively used to fulfill its continuing medical education mission.")

Dr Warren seconds Dr Tischler's position. "If they have the resources to do a program at all, it's not that hard to make speaker decisions, determine the content, get the grant money. At most it's two checks for each speaker. That's not all that big a deal." But he says companies often encourage providers to skirt the rules.

Why the Source of Payment Matters

"One of the most common deals we are offered is, 'Well, you're asking

for a grant for an amount covering an honorarium and expenses. Why don't you just let us take care of the expenses and send them directly to the doctor, and then you don't have to fool with it?' " Dr Warren says his response is direct: "I say, 'Well, that would imply that in some way the

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—Ted Warren, PhD,
Kansas Medical
Education Foundation

doctor is working for you, and we don't accept that.' "

While the technicality of who writes a speaker's check may not seem to be a serious issue to some, Dr Warren definitely believes it is. Ultimately, he says, "we're all in this together, and maintaining integrity is something we all have to do, or it disappears very quickly." ~

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View From Industry

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cusses it in terms of relationships: in other words, is the provider dependent on the company for future financial support?" he says. "So that's something that the pharmaceutical industry is going to be looking very closely at defining—

"CME providers are heavily dependent on financial support from industry. Would this reliance on support from company X in other departments create a potential conflict of interest—or at least, the appearance of influence—in terms of CME programming?"

—Brian Russell,
CoMed Communications

and how industry interprets that statement could lead to some very bad repercussions."

Among the factors the guidance lists as part of determining independence is whether program content had been influenced directly or indirectly through the nature of the relationship between the company and the provider. In other words, could the company's support result in a potentially biased content in the provider's CME activities? For example, does the provider have reason to believe that future financial support from the company depends upon producing programs that support the company's products?

Mr Russell maintains that

providers need to ask themselves some tough questions about their independence. "CME providers are heavily dependent on financial support from industry—not just through CME activities, but through research grants, fellowships, endowments, and so on. Would this reliance on support from company X in other departments create a potential conflict of interest—or at least, the appearance of influence—in terms of CME programming?"

Potential Impact on Funding

Mr Russell believes that the regulatory attorneys at individual pharmaceutical companies may impose a very conservative interpretation of the guidance to obviate any risk that the FDA might inquire into their CME funding. "Ultimately, it comes down to a question of individual integrity and professionalism. The problem is that it's going to leave so much up to interpretation that it may actually hurt the availability of funds for educational programming because the regula-

"What it boils down to is whether or not the program itself was created, developed, and carried out independent from the influence of the company. In other words, did you develop an independent, educationally sound program? As long as you can defend that, you're okay."

—Ilissa Bernstein
Senior Science Policy Advisor, FDA

tory people won't know how 'independence' might be defined."

Ilissa Bernstein, Senior Science Policy Advisor for the FDA, insists

that financial relationships will not be the sole determinant of independence. "What it boils down to is—despite the close relationship—whether or not the program itself was created, developed, and carried out independent from the influence of the company. If it was, then you are in a safe box. In other words, did you develop an independent, educationally sound program? As long as you can defend that, you're okay." ~

We are interested in our readers' thoughts on how to make a CME website more useful. What is your experience with CME on the Internet? What are medical professionals looking for when accessing a site? What would benefit the CME professional? Please forward your comments to:

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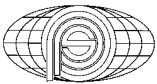
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