

CME BRIEFING

NEWS, OPINIONS, AND PERSPECTIVES IN CONTINUING MEDICAL EDUCATION ~ WINTER 2000

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

Evolving Medical Education and Communication Concerns Examined at Industry Seminar

By Chris McMorrow

A seminar sponsored by two pharmaceutical industry education associations attempted to put into focus a number of critical, unfolding policy issues affecting providers of continuing medical education (CME). These included the communication of medical information through CME programs, as well as regulation of prescription drug promotion and distribution of peer-reviewed journal articles and textbooks.

Held June 7-8 in Teaneck, New Jersey, the seminar, *Marketing of Prescription Drugs in the New Healthcare Environment*, provided more than 100 industry professionals and CME providers with timely insights on groundbreaking court

cases and ongoing policy debates affecting healthcare and physician communications.

Dissemination of Off-label Information: Where Things Stand

The ability of pharmaceutical firms to discuss freely with the medical community the latest clinical knowledge about the use of FDA-approved products for nonapproved indications, forms, or dosages is an increasingly important and heated issue. This is particularly the case in the areas of oncology and AIDS therapy, where some 90% of drug use is off-label.

Having won the first rounds in cases addressing freedom of speech, physicians and industry

professionals remain uncertain about how to promote the exchange of off-label information about pharmaceutical products and medical devices. In an attempt to clarify to seminar participants just how and when off-label medical information can be appropriately distributed, the faculty reviewed the status and impact of recent events, including Washington Legal Foundation (WLF) litigation and anticipated new challenges to the 1997 FDA Modernization Act (FDAMA) regulations.

Washington Legal Foundation Litigation

More than 4 years ago, the WLF, a nonprofit group representing pharmaceutical industry and advertising interests, brought a suit against the FDA, charging that certain agency limits on distribution of educational material by pharmaceutical companies were unconstitutional. The

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Distance Learning and CME Today

By Ash Madhok

Distance learning is not a new concept. Correspondence courses that offered adult education by mail were developed more than 150 years ago. Nevertheless, distance learning has undergone a profound transformation in recent decades as advances in communication technologies have revolutionized the speed at which teachers and learners can interact over long distances. Personal computers and improved communications technology are the

latest innovations to promote life-long learning by providing access to education anytime, anywhere, via the Internet.

Although distance learning is employed in many professions, it is of particular importance in medical education. This need has spawned a variety of media for "self-assessment" CME activities including journals, newsletters, videotapes, audiotapes, CD-ROM programs, and Internet-

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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.

Physicians World Communications Group is dedicated to health-related education for physicians, paraprofessionals, and patients.

Professional Postgraduate Services®, a division of Physicians World Communications Group, is accredited by the ACCME to sponsor continuing medical education for physicians.

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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case arose from concern on the part of physicians and members of industry regarding the FDA's seemingly overly restrictive limits on distribution of off-label information, as outlined in the FDA's Final Guidance for Industry regarding commercial support of scientific and educational activities and in the FDAMA.

Judge Lamberth's now-famous "WLF ruling," handed down in July of 1998 (and subsequent decision in July 1999), was landmark in that it not only put FDA regulatory power under enormous scrutiny, but also ultimately rejected the agency's two major arguments: 1) only FDA-reviewed and -approved concepts could be disseminated in accordance with a detailed set of criteria as outlined in FDAMA; and 2) physicians need to be "protected" from drug company misrepresentation of facts.

Three major clarifications regarding the rights of industry versus the regulatory power of the FDA came out of this decision, based on Judge Lamberth's view of off-label discussions as "commercial speech" protected by the First Amendment:

1. Pharmaceutical companies may freely distribute to physicians copies of articles from peer-reviewed medical journals containing discussions of off-label product usage.
2. In its capacity as grantor supporting development and implementation of CME programs, industry is free to offer suggestions for content and speakers for CME programs to providers and sponsors. However, because of ACCME requirements, responsibility for content and speakers rests with the CME sponsor, independent of influence from the commercial sup-

Pearson v Shalala

A lesser-known case, but philosophically as important as the WLF ruling, is *Pearson v Shalala*. This suit challenged the FDA's authority to regulate communication about dietary supplements rather than the ethical drug products and medical devices covered in the WLF case. Jonathan Emord, JD, who argued the case, provided a succinct summary of the impact of *Pearson v Shalala* at the New Jersey meeting. He explained that this case further eroded the FDA's ability to restrict speech regarding the role and use of supplements, provided that adequate disclaimers accompanied the communication. As in the WLF case, both the message and the intent of the court were clear. Dissemination of medical information, accompanied by appropriate disclosure, is fundamentally a first amendment issue of protected speech.

3. The FDA is within its jurisdiction to require disclosures of significant financial relationships between faculty and industry to ensure that off-label dissemination is not "false or misleading," including the fact that the company has an interest in the product and that the off-label use is an unapproved use in the eyes of the FDA.

Legal Challenges to FDA Modernization Act

On a separate but parallel track, FDAMA regulations outlining the practical implementation of off-label dissemination of medical information in peer-reviewed journals have continued to undergo legal challenges following last year's

WLF decision. These cases are still under appeal, making it difficult for manufacturers to be clear about how to proceed—that is, whether they should follow FDAMA to the letter or adhere to the principles of Judge Lamberth's rulings.

In late July of 1999, Judge Lamberth handed down his long-awaited ruling on FDAMA, which reinforced his WLF positions of the previous year. This order struck down both FDAMA and FDA's implementation of regulations related to discussions concerning unapproved uses of approved prescription drugs or medical devices. Reiterating his July 1998 WLF stance, Judge Lamberth maintained that FDA may not prohibit pharmaceutical or medical device manufacturers from disseminating or redistributing to physicians or other medical professionals any article previously published in a bona fide peer-reviewed professional journal or reference textbook—whether or not the materials include a significant or exclusive focus on unapproved uses.

“The government ... simply cannot justify a restriction of truthful non-misleading speech on the paternalistic assumption that such restriction is necessary to protect the listener from ignorantly or inadvertently misusing the information....”

Judge Lamberth

Roadblocks Contested, Not Eliminated

Eliminating FDAMA restrictions are justified in Lamberth's view that “The government ... simply cannot justify a restriction of truthful non-misleading speech on the paternalistic assumption that such restriction is necessary to protect the listener from ignorantly or inadvertently misusing the information.... This axiom is

Drug Marketing Seminar Agenda and Sponsors

The accompanying article concentrates on issues of importance to providers of medical education and communication programs—particularly litigation directed at the FDA and the FDA Modernization Act (FDAMA) regulations, which were discussed at last summer's seminar on *Marketing of Prescription Drugs in the New Healthcare Environment*. The seminar was jointly organized and sponsored by two groups, the Healthcare Marketing & Communications Education Foundation (HMCEF) and the Pharmaceutical Education and Research Institute, Inc (PERI).

Meeting organizer and program director Kenneth P. Berkowitz, Esq., Senior Counsel at APCO Association, Inc, presided over a faculty of 20 professionals and policy experts representing various government agencies, trade groups, law firms, and professional associations, including the Accreditation Council for Continuing Medical Education (ACCME), the American Medical Association (AMA), and the American Academy of Family Physicians (AAFP).

particularly powerful where the recipient of information is a sophisticated listener trained extensively in the use of such information, as are the doctors and other healthcare providers in this case.”

Judge Lamberth's order also is significant in terms of the other FDAMA hurdles it strikes down. For one, there is no longer a need for manufacturers to file a Supplemental New Drug Application for each off-label use, which has been viewed as a kind of “constitutional blackmail.” In addition, there is no requirement to prepare extensive bibliographies or detailed documentation of dissemination lists. Indeed, the only things the judge left standing from the original FDAMA legislation related to off-label information are the requirements that:

- commercial speech involved in the discussion of off-label usage not be deemed “false or misleading”; and
- manufacturers must disclose their interest in drugs or devices for which off-label usage is discussed, as well as the fact that such usage does not have FDA approval.

It is important to note that while

manufacturers may distribute “off-label” information that meets the requirements established by Judge Lamberth, their sales representatives are not allowed to use this information to promote the company's products.

While manufacturers might want to start cheering, most industry experts urge extreme caution until the dust from this case fully settles.

Regardless of the FDA's role, sponsors, industry supporters, and third-party providers of certified CME programs are still bound by the parameters and guidelines set forth by the ACCME and AMA.

They point out that although this ruling had been long expected, it is being appealed by the FDA. Furthermore, pharmaceutical company programs involving discussion of off-label uses are bound to be subject to enormous scrutiny in the

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CME Concerns at Industry Seminar

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aftermath of Judge Lamberth's ruling—and many are likely to seek legal counsel before proceeding with the design of such programs. Of course, regardless of the FDA's role, sponsors, industry supporters, and third-party providers of certified CME programs are still bound by the parameters and guidelines set forth by the ACCME and AMA.

Varied Perspectives on Professional Guidelines

The second day of the seminar featured a topic of particular interest to CME providers in the form of a panel on professional guidelines. Moderated by Clayton R. Hasser, Vice President for Publications and Communications at the American Academy of Family Physicians (AAFP), the panel featured five speakers who shared their perspectives on different aspects of CME.

Murray Kopelow, MD, Executive Director and Secretary of the ACCME, set the tone by reiterating the four basic principles to which

“CME providers are responsible for maintaining discipline among grantor firms.”

all CME providers must adhere: independence of planning, clear separation between education and promotion, provider control of funds, and need for full disclosure.

“All four areas tend to be problematic,” said Dr Kopelow, adding that new technologies certainly play a role. “When ACCME-accredited providers implement programs through third parties, such as Web masters who don't fully understand CME rules and regulations, you see infractions like ads appearing

on CME websites. We cannot stress enough that providers bear ultimate responsibility and are obligated to monitor these situations carefully.”

AMA, AAFP Concerns Aired

Dennis K. Wentz, MD, of the AMA talked about industry practices in developing education programs that violate the association's ethical guidelines. Dr Wentz noted that paying physicians to attend meetings, whether CME or promotional, is always wrong because it is perceived as a cash award, which violates AMA ethical standards.

Another area where providers get into trouble, according to Dr Wentz, is the definition—and use—of “consultants” for educational or other programs. For the AMA, consultants who are invited to speak or attend an event must have genuine credentials and be viewed by peers as experts, not simply be part of the pool of “all physicians who practice medicine in a given area.” Finally, speaker training programs should not involve paying honoraria (beyond basic expenses) to physicians undergoing orientation as faculty for future paid lectures. Only physicians serving as faculty, who actually “train the trainers,” can receive honoraria for speaker orientation programs.

Norman Kahn, MD, discussed the role of the AAFP as a national accrediting agency for CME. Before awarding coveted AAFP prescribed credits to outside programs, the Academy carefully reviews the hours dedicated to a program, which also undergoes a rigorous quality assurance review. Tight monitoring of complaints, as well as a random audit process, ensures that AAFP standards are consistently maintained and adhered to.

Shared Goals of Industry and Providers

Panelist Lauren Stevens, Esq, Assistant General Counsel of Glaxo

Wellcome Inc, stressed that industry and providers share a common goal of providing the highest possible level of care for patients. She bluntly warned her fellow industry members about the pitfalls of violating CME standards. “Companies who routinely violate ACCME rules are inviting the FDA to get involved in regulating industry's involvement in CME.”

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Stevens also had some sage words of advice for CME providers: “Don't give us detailed information about programs before we provide grants; if we know too much about the scope and content of an educational program, it puts us, as grantors, in a very bad light. And please don't ask our sales representatives to distribute enduring materials; these may be considered labeling by FDA and hence be regulated as such. Finally, if you ask for our suggestions for speakers, please also request that we provide you with full disclosure about our financial ties with those speakers.”

Martin Cernal, CEO of Physicians World Communications Group, parent organization of the ACCME-accredited Professional Postgraduate Services®, offered the provider's perspective. Cernal observed that the industry is already highly regulated but believes that it will certainly invite even greater scrutiny if “competition turns into greed.” He urged his peers to stand up for CME guidelines and insist on provider control over CME content. “CME providers are responsible for main-

taining discipline among grantor firms," he stressed.

The lively Q & A following the CME guideline panel sparked some strong responses. Dr Kahn emphasized the power and potential benefits of CME programs, explaining that physician attendees were more trusting of certified programs than promotional efforts; CME certification assures potential attendees that product information will be presented with fair balance.

In the area of gifts and physician inducements, common sense, as well as a sense of proportion, ruled the day. Panelists stressed that any gifts to physicians must be related to clinical practice rather than personal benefit. Likewise, food—in modest amounts and style—was acceptable at the very beginning or end of medical meetings, as opposed to so-called dine and dash pro-

Both CME providers and their industry partners should anticipate a period of uncertainty and intense scrutiny as politics and legal cases converge.

grams, which have given industry-supported CME a bad name, especially in the lay press. Finally, the question of selectively paying for CME participant registration was strongly frowned upon by virtually all of the panelists, unless the unrestricted educational grant were large enough to cover all attendees.

Where Do We Go From Here?

At the end of the day, the bottom-line message of the June seminar was clear. Both CME providers and their industry partners should anticipate a period of uncertainty and intense scrutiny

Coming up in *CME BRIEFING*:

- ***ACCME requirements v WLF rulings: Practical considerations for CME providers***
- ***CME FAQs (frequently asked questions): What is an industry supporter's role in CME? Where does appropriate help with program planning and implementation end and undue influence begin?***
- ***Are all providers created equal? The continuing controversy over whether commercial organizations should be eligible for ACCME accreditation.***

as politics and legal cases converge. While pharmaceutical companies may take specific steps to protect and defend their interests in the midst of evolving policy, the watchword of the day is caution—both in preparing programs and in documenting the flow of communications.

There is little question that continued scientific advances will fuel an ongoing debate about the

freedom of individuals and organizations to disseminate information about their products. CME providers have an interest in this debate insofar as improved communication of medical information has the potential to enhance the care of patients—which is what CME is really all about. ~

Chris McMorrow is Senior Program Director at Physicians World Communication Group.

Questions or Comments?

We are always interested in feedback from our readers. Do you have any thoughts or concerns about something that you read in CME BRIEFING? Or any wit or wisdom about the CME industry you'd like to share with your colleagues?

We want to hear from you!

Please forward your comments to:

Editor, *CME BRIEFING*

Professional Postgraduate Services®

400 Plaza Drive

Secaucus, NJ 07094

Fax: 201-865-3521

E-mail: ppscme@pwcg.com

Distance Learning

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based programs. All these media are a form of distance learning, and as such, they offer physicians many benefits, including convenience, flexibility, and cost savings.

Distance learning programs are also beneficial for CME providers and grantors. This is especially true of programs offered on the Internet, which have the added benefit of allowing the provider to develop an on-line relationship with the learner. Internet-based programs provide the opportunity to reach a much larger audience than through traditional seminars and meetings. In addition, they are cost-effective, with the expenses of developing and implementing the program amortized over a large potential learner base.

Growing Power of the Internet

Despite some early skepticism about CME on the Internet, the World Wide Web has become a well-established venue for medical communications for both patients and physicians. In addition to participating in CME programs, Web-savvy physicians use the Internet to consult with colleagues and opinion leaders without leaving their desks.

Using one or more of the many search engines available to any Net surfer, physicians can review clinical references, study data, and countless databases and healthcare information resources. Practice guidelines can be downloaded from the National Institutes of Health websites, as well as those of many professional groups. Slides, video clips, and other educational material can be accessed and archived for personal use or passed on to colleagues.

It is probably hyperbole to say the Internet has changed the way physicians learn, but it has certainly changed the speed and convenience with which they can access all kinds of medical information.

*“A fresh hope is astir. From many quarters comes the call to a new kind of education with its initial assumption affirming that **education is life**—not merely preparation for an unknown kind of future living. Consequently all static concepts of education which relegate the learning process to the period of youth are abandoned. The whole of life is learning, therefore education can have no endings....”*

Written by Eduard C. Lindeman, friend and colleague of John Dewey, in his 1926 treatise, *The Meaning of Adult Education*. Norman, Okla: Oklahoma Research Center for Continuing Professional and Higher Education.

On-line Distance Learning— Summary of Benefits

Benefits to Physicians:

- Access to nationally recognized authorities
- Convenience in time and location
- Individualized pace of learning
- Direct savings (travel, hotel, etc)
- Indirect savings (no loss of practice income)

Benefits to Sponsors and Grantors:

- Reach larger audience
- Relatively low cost
- Establish on-line relationship
- Database capabilities for on-line registration
- Potential for automated grading/evaluation
- Easily updated as new research information becomes available

CME is an important part of these myriad offerings.

Real-time Versus Archived Information

Computer-based distance learning falls into one of two categories: synchronous or asynchronous.

Asynchronous programs are the most common format for CME offerings on the Web. As the name implies, the program is prepared in advance and archived: learners participate in the activity at their convenience. Asynchronous programs may be accessed on Internet websites or by CD-ROM, or by CD-ROM with a Web link.

Synchronous Internet programs represent the cutting edge of distance learning. These programs use real-time audio and synchronized media (eg, slides, video, whiteboard applications, and other multimedia

formats) to provide live on-line education. Advances in communications technologies and the ubiquity of computers have been catalysts for the growth of synchronous learning, which allows speakers to present and discuss their research from any location in the world. Participants can express their opinions, ask questions, and immediately receive a response during the event.

Until recently, synchronous distance learning programs have been bedeviled by technical challenges, but more powerful PCs and greater standardization among software programs and Web browsers are addressing these limitations. Synchronous programs can now be accessed on the Internet with commonly available Java-enabled browsers such as Netscape Navigator® or Microsoft Internet Explorer®. Although faster is always

better, some sites offer synchronous CME events that can run adequately with Internet connections as slow as 28.8 Kb.

Commercial Sites Offering Medical Information

Computer-based CME has all the benefits of other forms of distance learning, plus several distinct advantages, particularly for CME providers. For example, it can be made available 24 hours a

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day, 7 days a week, potentially anywhere in the world, at relatively low cost. It provides database capabilities and the potential for on-line registration. It allows program tests and evaluations to be retrieved and tabulated instantaneously. Finally, it allows enduring materials to be updated in a timely fashion at low cost.

Because there are so many medically related websites—with new ones constantly appearing—it is impossible to provide a comprehensive listing. Most universities, medical schools, and many hospitals have their own websites, often with links to other sources of CME. Similarly, the AMA and various specialty medical organizations provide access to on-line CME, as well as listings of traditional CME events.

Following is a list of some of the better-known commercial sites offering on-line medical information. *No representation is made about the quality of information at these sites.* The same standards that apply to

any other enduring materials should be used to judge the quality of CME programs on the Web. Physicians who wish to download information for patient education from the Web would be well advised to review the material carefully before distributing it.

- Medscape®: www.medscape.com
- WebMD®: www.webmd.com
- Physicians' Online®: www.po.com
- Cyberounds®: www.cyberounds.com
- Healthgate®: www.healthgate.com

Some companies that provide the technical platforms for synchronous learning programs include:

- Horizon: www.horizon.com
- Centra: www.centra.net
- Databeam: www.databeam.com
- Netpodium: www.netpodium.com
- Conceptis: www.conceptis.com
- Interwise: www.interwise.com

Future Directions

Traditionally, the primary means by which physicians have obtained continuing education is through medical

meetings, symposia, grand rounds, dinner conferences, weekend seminars, satellite symposia, and the like. These traditional CME mechanisms have proven highly popular because they allow physicians to immediately challenge concepts presented by the faculty and they are conducive to dialogue with other participants.

The Internet is not likely to supplant these forms of CME, but it can supplement them. Increasingly, the Internet is becoming a valuable resource for healthcare professionals, providing them with a convenient, inexpensive general medical resource and learning tool. For now, the majority of these CME offerings are asynchronous. In the future, as the technology continues to evolve, synchronous programs are likely to become more popular, as they combine the real-time interactivity of a live meeting with the convenience and cost-effectiveness of “old-fashioned” distance learning via print media. ~

Ash Madhok is Director of Digital Media at MediSpin Inc.

Evaluating the Quality of CME on the Internet

Whatever the format or topic, whether synchronous or asynchronous, CME on the Web should meet the same rigorous criteria as any other enduring materials. The following is a checklist of selected factors that should be considered when evaluating the quality of an Internet-based CME activity:

- Educational needs and learning objectives: Does the program clearly describe the content that will be covered and knowledge that will be imparted?
- Timeliness: Medical information can become rapidly outdated. Are the dates of original release and subsequent updates readily available?
- Accreditation and designation statements: Is the CME provider accredited by the ACCME or, if appropriate for the target audience, a state medical society? Is the program designated for AMA credit and/or comparable credit from other professional associations?
- Disclosures: Is the source of funding for the program stated clearly? Are there statements listing any significant financial relationships between the program faculty and corporate grantors?
- Clear separation of advertising and editorial content: Does the site adhere to the ACCME standards for commercial support of CME? For example, does the screen design separate advertising, including “banner” ads, from the CME activity?

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