



(l-r) Alan Breier, MD, chief medical officer, Mike Bigelow, assistant general counsel, and David Garza, manager of medical education

For Eli Lilly, innovation is in the blood. In 2004 the Indianapolis firm, the 10th largest pharmaceutical company by US sales, decided to act on what is now a natural instinct among life science companies: posting clinical trial data on the Internet. Its industry-first spawned a trend throughout pharma and biotech.

“In a very short period of time, we went from not having clinical trials and clinical trial results in the public domain to being besieged, and it hit me at one point that this is now the norm,” says Alan Breier, MD, Lilly’s VP, medical, and chief medical officer.

Lilly would like to spark a similar trend with its CME registry, which appeared May 1 and opened the files on \$11.8 million worth of grants given to 495 organizations during the first three months of the year. The firm pledged to update data on a quarterly basis. “It seemed like the same sort of sea change was possible [in CME],” says Breier.

Indeed, this may be a watershed moment. Pfizer executives hope to incorporate disclosures for 2008 education grants, pending approval from senior management, and CME execs from Wyeth, Novartis and Shire say they plan to go public, too, along with some grant recipients such as patient and physician groups.

Lilly and others say openness is needed to counter misperceptions that CME funding is a tool for promotion. Ever since PhRMA, the trade group, discussed industry funding of CME in its 2002 code, followed a

Recipient	Program/Description	Individual Program Amount
Foundation
Research Foundation
Johns Hopkins Medical Center
Univ of Illinois
Harvard University - Joan C. Edwards School of Medicine
Massachusetts General Hospital
Massachusetts General Hospital - Department of Psychiatry	...	\$825,000
Massachusetts General Hospital - Kenneth S. Schwartz Ce
Mays Clinic - College of Medicine
Mayo Clinic - School of Continuing Medical Education
Medical College of Wisconsin - Pediatric Endocrinology
Medical Education Conferences, Inc
Medical Education Resources, Inc
National Council of Pennsylvania

Eli Lilly’s CME grants registry shows Massachusetts General Hospital’s psychiatry department received the largest single grant, \$825,000 for a year-long educational program with some 150,000 registrants.

year later by the Office of Inspector General’s compliance guidance, which outlines the government’s expectations around commercial support for education, the media have ratcheted up criticism of CME. A number of high-profile marketing scandals provided grist for the mill. It all culminated in a Senate Finance Committee inquiry, which ended in April, and a Senate Special Committee on Aging hearing in late June.

In CME, the drug industry has another opportunity to bolster its

PHOTO LEFT: GREG PEREZ, TWIN PHOTOGRAPHY

MEDICAL EDUCATION REPORT

CME'S OPEN GESTURE

This year, to counter public skepticism, Eli Lilly revealed its educational grants in an online database. Now the transparency wave may be gathering steam, with other pharmaceutical firms, as well as patient groups and societies, saying they may make grants public, too. Will the efforts help restore trust in CME? **Marc Iskowitz** reports

Grant disclosure: Phenom or fad?

Eli Lilly is hoping its decision to launch an online CME grants registry at www.lillygrantoffice.com sparks a trend within Big Pharma. Here's a look at other organizations considering CME disclosure.



Pfizer's Cathryn Clary, MD, MBA, SVP, US Medical

"I really applaud Eli Lilly for [disclosing grants]. Pfizer is considering a similar type of transparency. We're actually looking a little bit broader than CME. In the last six months, we put our pipeline out on the Web... We put access to our post-marketing commitments [online]... Clinical trials disclosure is another thing... Everything that we do is going to wind up being very open and transparent to the public. Pharmaceutical companies right now are very, very interested in being as open and as transparent as we can be, because we feel we actually

have an excellent story to tell around drug safety, clinical trials and innovation. The same is going to apply to CME."



AstraZeneca's Pamela Mason, director, Medical Education Grants

"We place great value on individual integrity, ethical conduct and full compliance with the laws, regulations and guidelines that govern the US healthcare community, and we are looking across our business at ways in which we can be more transparent than we already are... We do not anticipate changing our approach to supporting [education] at this time. The idea of transparency meaning clearness and simplicity is an important one and may help to elevate the recognition of the value of CME and the value of the appropriate roles of providers and supporters with the end result of collaborating to improve patient care."

flagging trust levels. "All of the noise around this was so negative, and yet a lot of good from the funding that we provide to these groups—there was a real disconnect there," says Mike Bigelow, Lilly assistant general counsel. "We were, frankly, just looking for a way to get out ahead of the issue a little bit."



"If providers are concerned about information being public, that's a good litmus test of the strength and validity of their programs"

—Steven Singer, PhD, PeerPoint

With just over a billion dollars invested in 2005, according to figures from the Accreditation Council for CME (ACCME), CME is not drawing as much as some of the industry's other disciplines. The level of controversy surrounding CME, though, belies its size. Journalists, bloggers, academics and lawmakers have criticized it as a covert method for influencing prescribing, and that is the great question roiling the profession today.

A hot potato

Does transparency really help counter that notion? Providers were mostly of the same mind on the issue.

What Lilly is doing resolves the issue, but its action means that the spotlight is on providers now, asserts Steven Singer, PhD, director, education services, PeerPoint Medical Education Institute. "They're forcing transparency, passing the hot potato to the provider. If providers are concerned about that information being public, then that's a good litmus test for the strength and validity of their medical education programs relative to improving patient care."

Pri-Med, the Boston-based medical education and communications company (MECC), secured a total of \$976,285 for several activities on erectile dysfunction, depression and pain and diabetes, according to the

Lilly registry. An official says that more contextual information would have been useful to back the independence of each grant. The registry simply lists the grantee name, amount and a short description.

"I think the intent was transparency from the financial perspective. That is good," says Marissa Seligman, PharmD, Pri-Med Institute chief clinical and regulatory affairs officer, "but when disclosing CME support, it is almost [as] important to provide details beyond the finances, such as accredited provider, target audience, educational objectives and duration of the grant. It is important for the public to understand why the grant monies are being set forth, i.e., which educational gaps are they intended to support."

Breier counters that Lilly's strong policies and procedures ensuring the independence of CME are sufficient to instill confidence. "We do not support educational activities [that promote] our products," he says. "And [we] have all of the safeguards in place to ensure that that doesn't happen. So by going public... hopefully we will be able to change some of those misperceptions."

Lilly has no role in influencing content or speakers, Breier adds. Decisions about which programs to fund are made by its medical officials, not its marketing department. Ninety percent of funding goes to accredited education. None of it is spent to promote the company's products. "We're on course this year [to provide] 3,000-4,000 grants that will total \$50-\$60 million," Bigelow says. The company, like most grantors, focuses grant money in therapeutic areas of expertise. Breier says Lilly is expecting its funding levels to remain constant this year, as they have for the last two.

Lilly says providers support its decision. "Maybe at first, before they really understood the reasons behind [disclosure], there may have been some concern on their part, but I didn't get that after I talked to them," says David Garza, Lilly manager of medical education. "They were very much on board with our decision."

Senate report

The Senate Finance Committee was impressed, too. Sens. Max Baucus (D-MT) and Charles Grassley (R-IA), the ranking mem-

bers of the committee, said in a statement that they hope that other drug companies will take similar action.

They were less sanguine, though, in their April report, concluding that pharmaceutical companies support CME activities as a way to broaden their markets. “Drug companies routinely fund educational grants to support programs that favorably discuss the companies’ newer and more lucrative products,” the report stated. It had measured praise: “This report shows some separation between medical education and marketing efforts, but this process isn’t clean enough.”

But the senators reserved their harshest criticism for CME oversight, which they found to be largely ineffectual: Educational grant programs are not pre-approved or directly monitored, and “oversight actions may occur long after the problematic educational activity occurred,” taking as long as nine years from the noncompliant activity for a provider to lose accreditation.

Evaluating the stringency of rules was at the top of the ACCME’s agenda when its board met last month to discuss a response. The group may wind up tightening its accreditation process rather significantly. Murray Kopelow, MD, ACCME chief executive, told *MM&M* in May that considerations include placing monitors in audiences and toughening the Standards for Commercial Support: Standards to Ensure the Independence of CME Activities. (The meeting was set to convene after this article went to press.)

In the months preceding the July meeting, ACCME requested comment from accredited providers on rules governing the relationship between providers and commercial interests, a move some say portends future refinements to the SCS.

Another response ACCME is looking at is disclosure. “Trans-

parency is always good,” said Kopelow. “People talk about sunlight being a good solution to a problem. ACCME will definitely consider making public [the] accreditation status and compliance findings of accredited providers to the extent this might be of value to the system.”

The FDA’s general counsel, Sheldon Bradshaw, said his agency also may rethink its rules concerning companies involved in funding education—encapsulated in a set of 1997 guidelines. “Does the FDA...need to be more vigilant in these areas? Perhaps,” he said at a CME industry meeting in May. Whether its role will change significantly is less likely, though. Bradshaw said that while the FDA has an interest in making sure CME is not a shill for promotion, “This is a complicated area. The agency itself is walking a delicate line in making sure we’re protecting



“ACCME will consider making public the accreditation status and compliance findings of accredited providers”

—Murray Kopelow, MD, ACCME

the First Amendment rights of [CME] providers.”

However, the Senate seems to have left the door open for FDA involvement, and some expect it. “I see a resurgence of the role of FDA in terms of promotional education,” said Marty Cearnal, EVP, chief strategy officer, Jobson Medical Information. “With a new commissioner, FDA will take a stronger position there, like it did around DTC.”

CME glasnost

CME glasnost may not be a phenomenon yet, but at the very least, it’s triggering some extended conversations in med-ed circles (See sidebar, “Grant disclosure: Phenom or fad?” on p. 39). It began in 2006, as Lilly executives huddled to review the firm’s response to a second round of questioning from Sen. Grassley during the Senate’s two-year inquiry of CME.

A number of the people who had worked on the clinical trial registry, which launched in January 2004, also were involved with the grant program. One of these people was Bigelow. He saw an opportunity to again highlight Lilly’s role in an important area.

As with any large initiative, buy-in from executive leadership was crucial. Breier chaired the internal working group responsible for launching the grant registry.

It couldn’t have come at a better time. CME is being scrutinized and debated as never before. At its June hearing, the Senate Special Committee on Aging, led by Herb Kohl (D-WI), alleged a conflict of interest in sponsored CME. The senator favors transparency, as well, and is pushing for a national registry of gifts to physicians that would include educational payments made by industry.

Around the time Lilly was populating its registry, a number of educational initiatives funded by Pfizer’s \$21 million Neurontin settlement, which Pfizer inked in 2004, were getting started. One of these is PharmedOut.org, a nonprofit Web site that offers links to non-com-

Five tips for disclosure*

- 1 Back up disclosure with compliance:** Before increasing public access to your grant information, grantor and provider policies and procedures should be in place to ensure educational dollars are not being used for promotion.
- 2 Assure buy-in from executive management** Eli Lilly VP, medical, and chief medical officer Alan Breier, MD, chaired the internal group responsible for Lilly’s online grant registry initiative
- 3 Put providers on notice** Letters of agreement (LOAs) should put providers on notice by stating that grants they receive may be disclosed at some point.
- 4 Commit to regular updates** Re-populate the database regularly and start with at least a full quarter of data. Consider providing details beyond finances, such as accredited provider, target audience, educational objectives and duration of grant—all of which help the public see why the grants are being provided.
- 5 Listen** Collect feedback from providers at industry conferences as to whether they support your initiative, why or why not and how you can refine it.

* For a grantor
Source: *MM&M* reporting

mercially supported CME. “Part of what we’re planning to do is to expose some of the techniques used by industry to influence physicians,” said Adriane Fugh-Berman, MD, the associate professor at Georgetown University Medical School who runs the site. By improving public access to grant information, Lilly’s move at least shows it’s responding to voices like PharmedOut.org.

Changing the debate

To be sure, transparency has its pitfalls. There may be a potential for embarrassing disclosures when it’s easier for regulators as well as the media to see how much a company is spending, topics it’s spending on and who’s getting the grant.

Another concern is that public perception of grants could possibly affect grant decision-making, skewing it toward academic institutions or societies. Lilly refutes that idea.

“It’s not going to make any drastic changes,” says Garza of his firm’s openness. “As long as they offer good proposals, MECCs will not get any less than societies or medical schools,” he assures. “What we’re hoping, though is, now with information being public and [with anyone] being able to see what other providers are supporting...that the quality of programs goes up...so hopefully it raises the bar on what types of things come in front of us.”

The biggest hoped-for impact, though, is changing public perception. “[The public] may question whether the funding by the industry of CME is or is not the right thing and whether those safeguards are ultimately adequate to ensure that that’s the case,” Bigelow says. “But



“The best thing industry can do is let the CME community show us what quality education looks like”

—Mike Saxton, MEd, FACME, senior director, team leader, medical education, Pfizer

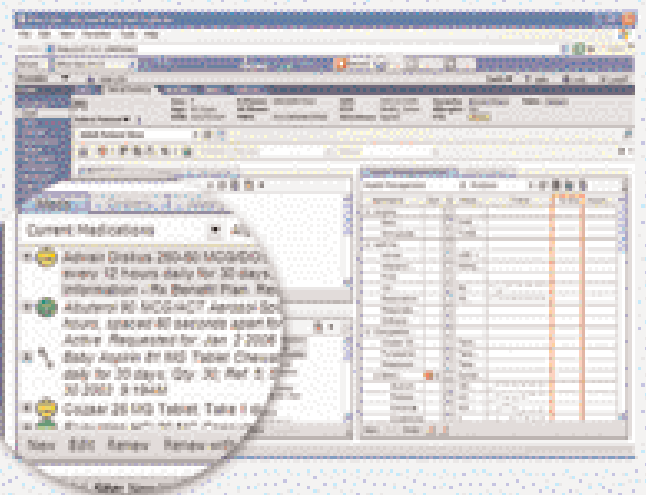
hopefully at least some of the cynicism...will go away.”

Some, but probably not all. As long as pharma directs CME funding toward therapeutic areas in which it has a commercial interest, either marketed products or those in development, it will be vulnerable to accusations of subtly influencing the national curriculum. Even Wyeth’s experiment last year with block grants, a system where the company removes itself from individual grant decision-making, was directed at one area, diagnosis and treatment of depression and anxiety. (Wyeth markets Effexor for major depressive disorder.) Additionally, no amount of sunlight seems likely to negate the complaint that some continue to break the rules in place to ensure CME independence.

The next trend

There is an area where regulation is already taking a strong stand: outcomes. In its 2006 updated compliance standards, the ACCME encourages providers to participate in quality and patient-safety improvement or, at least, to document contributions to shifts in competence, performance-in-practice and/or patient outcomes.

Bring on the patient data: Pri-Med and Allscripts pilot new research tool



One of the biggest challenges in demonstrating patient impact from an outcomes perspective is accessibility to patient-level information.

“Without having a closed system, it makes it increasingly more difficult to actually get access to what the physicians are doing in their practice and what their patient populations look like,” says Anne Goodrich, group director of physician insights, Pri-Med.

By partnering with electronic medical records firm Allscripts, the Boston-based provider is helping lower that barrier. Like many providers, Pri-Med wants to measure patient impact from a needs-assessment and an outcomes perspective.

However, “It’s cleaner to start an investigation of patient-level analysis with needs assessment first,” Goodrich explains. “It allows us to truly understand what kind of information we can yield without making assumptions about the quality of the information or its validity.”

Their pilot explores diabetes, hypertension and dyslipidemia, clinical areas with measurable metrics. In diabetes, for example, the EMR database will offer a glimpse of the percentage of patients who are having A1C values measured twice in 12 months, per national guidelines.

Additional insight

Pri-Med hopes the additional layer of insight augments its traditional needs assessment and enhances its ability to educate around learning gaps. It then may be possible to leverage this type of analysis for outcomes.

That will involve looking at two snapshots: the practitioners who were not exposed to the education and the ones who were and comparing their patient populations to see whether or not an educational intervention delivered against the identified gaps uncovered through the needs assessment.

That’s easier said than done. Data partners must have practitioners in the same markets where the education is taking place, and enough of them to match participants in the CME activity. Participant and non-participant groups must mirror each other enough demographically to be valid.

For now, the partners are taking it one step at a time. Says Goodrich: “We really need to understand and evaluate this type of analysis and iron out the kinks.”

That has paved the way for more collaboration between providers and non-educational entities like health systems, managed care or quality assurance—between those that have access to physician change or patient data and those that don't.

“The next trend will be collaboration, as education hasn't caught up with the regulations yet,” says Mike Saxton, MEd, FACME, Pfizer senior director, team leader, medical education.

The data that could come out of these partnerships will determine the future of commercial support for CME, since drug firms want a demonstration that their funding changed healthcare provider attitudes, knowledge or behavior. “The best thing industry can do is let the CME community show us what quality education looks like,” Saxton says. “If we award grant dollars to performance-improvement-oriented CME, it benefits patients.”

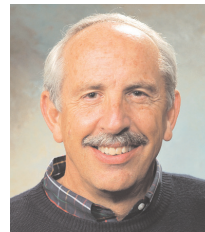
Even though the new ACCME outcomes standard won't become binding until 2008, providers already see the writing on the wall. “To continue receiving support, we'll have to provide more compelling data on program needs and learning outcomes,” says Marcia Jackson, PhD, senior advisor, education, American College of Cardiology (ACC). (See the sidebar, “Bring on the patient data,” on p. 43 for an early look at how this is being approached.)

As more stakeholders interested in improving healthcare quality get involved with CME organizations, educational funding may become more balanced. “If we in CME can start demonstrating value, there is an opportunity for more internal and organizational funding,” says Carol Havens, MD, director, clinical education, Northern California Kaiser Permanente. “As physicians see the benefit, they may be more willing to pay for it.”

Saxton says commercial support for CME—which rose just 4% to \$1.1 billion in 2005, the most recent data available—will continue to wane as new, non-pharma sources increase. Pharma accounts for 49% of the \$2.25-billion in CME revenue, down from 54% in 2004. The rest

comes from advertising and exhibit fees at meetings as well as from registration fees. “I expect to see the first actual decline in commercial support in the 2006 ACCME data,” he says.

According to Lilly's Garza, the biggest focus for the Lilly Grant Office is funding “innovative programs that are really getting to the outcomes measures,” that show the learning objectives close the gaps and that “we have quantifiable data that we're making a difference in



“Some organizations are making a decision to get out of CME because they don't have the skill sets or the funding”

—Joseph Green, PhD, ACC

patient outcomes and quality of practice.”

But, since most providers all still trying to figure out the most cost-effective way to address outcomes measurement, he adds, “not a lot of innovative programs [are] being brought to us yet.”

Another bright spot for CME is the increasing ubiquity of education. Between 2005 and 2007, there has been a 24% decrease in offline meeting attendance and a 25% rise in online meeting attendance. “That's nearly a one-for-one shift away from offline to online conferences,” observes Meredith Abreu, VP of research at Manhattan Research, the company that ran the study of 1,353 practicing US physicians. “With the stringency of ACCME standards, it's less attractive for physicians to travel to these events. Certainly convenience is paramount.” (For more on electronic media use, and a roundup of other CME trends, see the CME Guide 2007, a supplement to the May issue of *MM&M*.)

If industry wants to enlist Web 2.0 in its effort to convince others that grants for educational purposes are an important service, it has a ready

The ‘familisimo’ factor: Bringing culturally sensitive education to Latinos

Most medical education programs concentrate on healthcare professionals, assuming that a better trained medical provider benefits patient care. Organizers of a new, independent CME program funded by Sanofi-Aventis, however, decided to include patients as attendees. That's because in the Latino community, the usual assumptions don't apply, especially when it comes to diabetes, an increasingly prevalent disease in this population.

People in minority communities express more of an aversion to insulin therapy, explains Dana Philipps, PhD, clinical communications specialist with CPE Communications, which is producing the program.

“Latino populations tend to not get the early intervention or screening, or be on top of glycemic control, as much as non-Hispanic whites,” says Philipps.

To prevent serious co-morbidities with type 2 diabetes,

CPE's effort, starting next month, is designed to ensure that patients understand disease progression and control. The program will be divided into two parts: physicians in the morning, and patients, their families and community members in the afternoon.

“We realize that the patient is very involved with their family,” says Carol Seabury, EVP, CPE Communications.

This and other cultural values “may impact [healthcare providers'] view of the disease, treatment and self-management,” adds Amaryllis Soto, senior national education manager, diabetes, for Sanofi-Aventis, which markets insulin products Lantus and Apidra.

CPE is trying to recruit bilingual faculty, or at least have on-the-spot translation of their talks. Lectures will incorporate opportunities for professionals to reflect on what they are learning, such as breakout sessions, while patients will see exhibits like cooking demonstrations and potentially a demo of insulin pens or A1C testing.

Venues selected are McAllen, TX (on the Mexico border), Miami and the Bronx, NY—“[We are] really trying to go into the heart of the Latino/Hispanic communities where this can have its greatest impact,” says Sheri Neher, CPE client services director.



audience: 80% of physicians watch video online, and they love reading blogs from other doctors or KOLs, according to Abreu.

Grantors and providers have more to do if they want to keep pace with, and stay ahead of, regulations. With the same fervor as critics are attacking sponsored CME, some in the industry are working to bolster competencies.

This summer Pfizer is making its CME grant reviewers re-interview for their jobs, and candidates are being required to meet a higher standard that includes three years experience and at least a master's degree in education. The bid to raise qualifications is one way to ensure compliance with external and internal policies and procedures and to ensure that those assessing grant requests have educational expertise.

Raising competencies

Providers are also rallying. The ACCME wants organizations, especially those closest to patient care such as hospitals and medical schools, to link CME with quality care. A number of CME's best minds are taking up national leadership positions to help strengthen that link. Dave Davis, MD, is leaving his post as head of CME at the University of Toronto and a successful medical practice to join the Association of American Medical Colleges (AAMC), which oversees several national initiatives aimed at improving medical education.

Joseph Green, PhD, a CME consultant who is soon to take over as VP for professional development and chief learning officer for the ACC, will work to tie CME to physician performance and quality of care as he seeks to improve education for the college's 33,000 members. Both men cite the ACCME's updated compliance standards as impetus for their moves. Green acknowledges that, for some providers, it will be very difficult to survive the new environment. "It's going to be rough," he says. "Some organizations are making a decision to get out of CME because they don't have the skill sets or the funding."

Indeed, CME is much more complex than it was 20 years ago. All accredited providers must be compliant with SCS and other regulations, and these rules can be moving targets.

The National Commission for Certification of CME Professionals (NC-CME) is a non-profit whose goal is for every provider to have someone on staff who is certified in a group of core competencies. The group has formed a partnership with the National Board of Medical Examiners to look at different strategies for developing and validating an exam. A summer working meeting is planned at which the group will seek to identify strategies for moving forward. The group wants to offer its first true beta test after the first of the year.

Virtue and vice

If trust is transparency's main virtue, its main vice may well be sunlight. Minnesota, the first state to pass physician gift disclosure laws, wound up the subject of an unflattering *New York Times* exposé. But education revelation could be good for the CME industry if it acts as a deterrent against rule breakers and boosts pharma's PR play book, which most agree could use some new moves. To his counterparts across the industry, Breier has this to say: It's no time to be meek. "We think we're enriching the healthcare environment," he says. "We're not bashful about that." ■

Do live lectures still work? (We found out.)

Lectures can be useful, but educators must match instructional design with learning objectives to reap maximum benefit, said a panel of experts.

Why did *MM&M* devote an hour-long, live Web cast to understanding lectures? Lectures are the most heavily funded of all CME media and the one most beloved by healthcare professionals, research shows.

But there remains a need for clarity around their proper use, said Anthony Iacono, president, Access Medical Network. For instance, in a 1999 journal article, Dave Davis, MD, was quoted as saying that didactic lectures were shown not to change physician behavior. He said recently that those comments have been misinterpreted to mean that live lectures don't work.



Iacono

In addition, commercial supporters may at times feel compelled to support live meetings at association events "to show a presence if nothing else." For these reasons, Iacono said, "it's important not to confuse their role and to discuss how to make them more effective."



Schmidt

When there is a need to convey basic and new information, lectures can be quite valuable, said Hilary Schmidt, PhD, associate VP, medical education, Sanofi-Aventis. "A didactic lecture is likely to play a more significant role in addressing a knowledge gap than a competence or performance gap." In the latter cases, other interventions are also needed (Web, print media, podcasting, TV).

Regardless of the medium, educators should include self-reflection and follow-up tactics and make learning sequential.



Lockyer

Learning is indeed mediated by the type of intervention and level of interactivity, as well as by the number of participants and number of sessions, added Jocelyn Lockyer, PhD, director, CME and Professional Development, University of Calgary.

But the role of the lecture is not to produce major change. "For most physicians, it consolidates learning and often validates what they already know," she said. "It rarely leads to profound changes."

On the other hand, they can be "an extremely efficient way of communicating basic and new information," Schmidt said. Style makes a huge difference. "A lecture can put you to sleep. Even the really good ones can be forgotten 24-48 hours after the event."

Lectures should be easily understood and easy to remember at a time when the information will be most relevant. Injecting interactivity and reflective techniques, as well as follow-up activities that build on the learning, can help drive behavior change.



If you missed the April 30, 2007, Web cast "Is Live CME Still Effective?" or just want to hear it again, an archived copy is

available. Just insert the following link, <http://www.mmm-online.com/Webcasts/section/76/>, into your Web browser, or go to [mmm-online.com](http://www.mmm-online.com) and click on "webcasts" under the "events" menu.