

**THE END
OF CME
AS WE KNOW IT**



Pfizer's recent decision to pull the plug on direct funding of CME through independent commercial providers follows months of public criticism of pharma support. **Lew Miller** and **Warren Ross** explore how the rest of the industry is coping with the assault

Even before Pfizer's bombshell announcement at the end of June that it was cutting off support for CME programs run by commercial providers, 2008 was shaping up to be an ugly year for the medical education business. To be sure, there were a few infusions of sanity—notably, the American Medical Association House of Delegates' resounding rejection in June of a Committee on Ethical and Judicial Affairs proposal that industry funding be purged from CME. But for the most part, it's been a steady drumbeat of opposition to industry-supported continuing education.

On April 16, the *Journal of the American Medical Association* published an editorial that not only called on professional organizations and CME providers not to “condone or tolerate” input on content of educational materials from for-profit companies but even to refuse their financial support. Meanwhile, a bill was introduced in the Massachusetts legislature banning industry gifts to doctors. Several Yale and Harvard scientists announced they would no longer accept speaking fees from healthcare companies, and Memorial Sloan-Kettering Center in New York became the latest institution to let it be known that it would no longer accept industry funding for its education programs. Then in May, Sens. Chuck Grassley (R-IA) and Max Baucus (D-MT) reintroduced their Physician Payments Sunshine Act requiring public disclosure of gifts to physicians. This new version defines participation in industry-supported CME as a form of payment.

To paraphrase a once-popular political slogan, “Industry Out of CME” seems to be a growing refrain among its critics, and as a result echoed among at least some of the marketing people who have been allocating the money. “If we can't even suggest a topic or a speaker,” one company executive responding to the latest accreditation standards was quoted as saying, “why should we fund such education?”

At this point, a definition is in order. The term certified CME applies only to programs from accredited providers for which physicians are given AMA credits, necessary for relicensure, hospital privileges and sometimes for specialty recertification. Educational programs that don't conform to the restrictive criteria of the Standards for Commercial Support of the Accreditation Council for CME (ACCME) may be equally valid but are now designated promotional medical education.

This category would include programs that are intended to inform doctors about specific products, such as symposia to instruct doctors how best to use new drugs.

ACCME accredits CME providers and requires them to adhere to standards for independence that now keep industry supporters from having any input on the content of CME programs or selection of speakers; they also call for disclosure and resolution of any financial conflicts of interest on the part of program organizers and presenters. Yet even these stringent ACCME efforts to prevent bias have been criticized by the Senate Finance Committee and others on the grounds that there is inadequate policing. No wonder the pharma industry has become more reluctant to support certified CME. Compliance officers have responded to the threat of federal lawsuits by insisting on separating grants for CME from marketing, and now let the grants be administered by their professional education divisions.

In light of these trends, *MM&M* asked a group of knowledgeable industry education professionals for their response to two questions:

1. Given the current climate, how do you assess the value of industry's (and specifically your company's) investment in medical education?
2. What changes in the CME system would make industry's (and your company's) investment more productive?

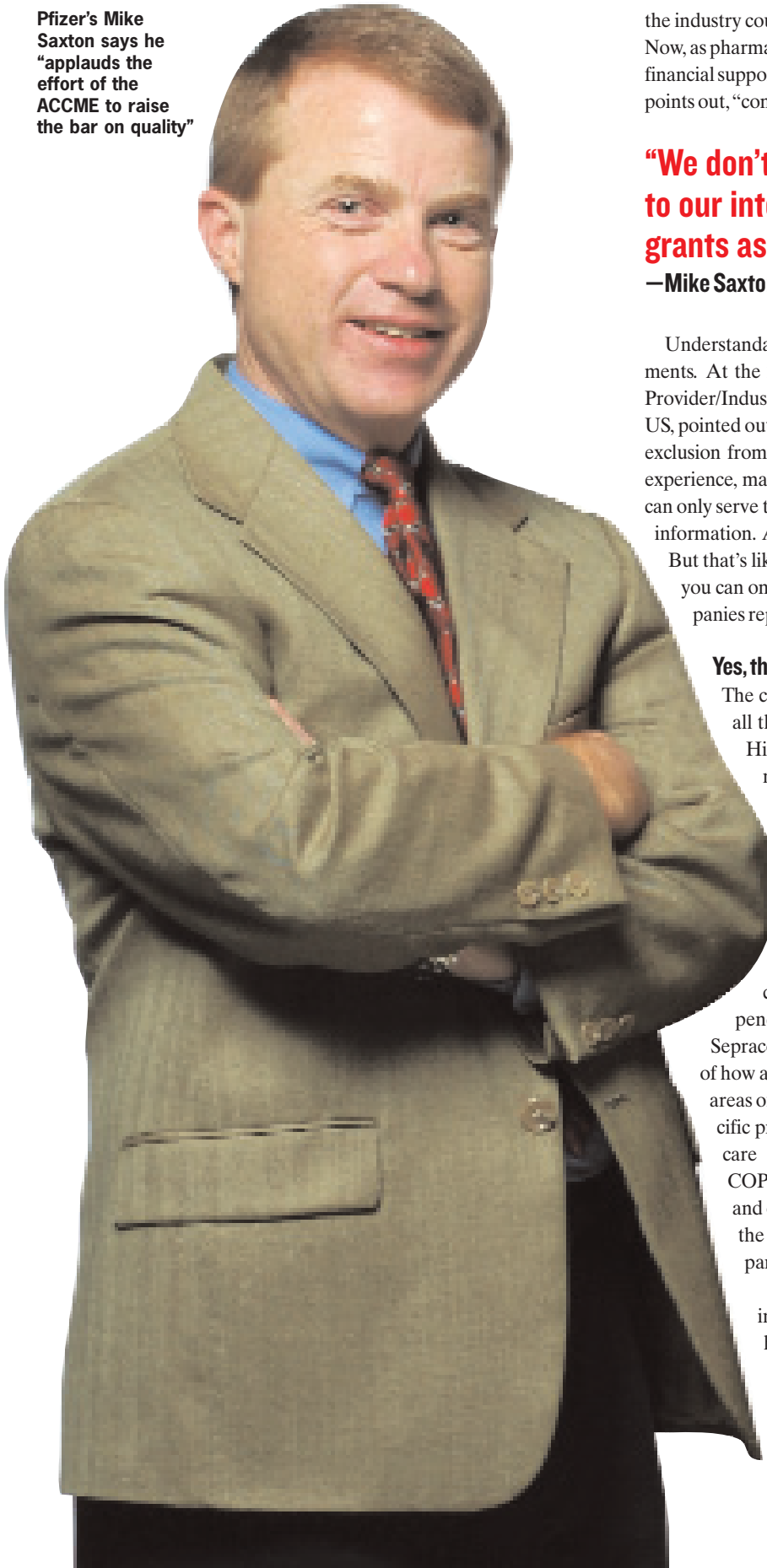
As David Schlumper, director of educational development, Quintile Medical Education, replied: “The first thing we should be asking is: ‘Does the education benefit the patient?’ If it does, how can you challenge it?” Well, it is not only being challenged but so severely restricted that its future is in doubt, and to understand how we got to this point it helps to review the evolution of the CME credit system.

The other credit crunch

It all started in the 1960s with the AMA's Professional Recognition Award, designed to encourage doctors to keep up with medical advances. It was a simple system of credits which AMA itself administered. Then, in the mid-70s, states began to demand such credits as a requirement for relicensure. That, in turn, led in the 1980s to a tighter system of accrediting providers to be administered by ACCME—a new organization formed by the AMA and six other national healthcare organizations. The influence of industry on CME was not fully addressed until the early 1990s, when the first Standards for Commercial Support were issued, to reduce perceived bias in CME programs that favored industry's interests.

Nonetheless, industry funding continued to grow in the 1990s, topping \$1 billion in 2006, but the 2007 revisions—eliminating influence

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the industry could have over content or speakers—reversed the trend. Now, as pharmas are doing their best to comply with the new standards, financial support of CME appears to be declining, though as Schlumper points out, “companies are all over the map in interpreting” them.

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—Mike Saxton, Pfizer

Understandably, many in industry are not happy with the requirements. At the 2005 conference of the National Task Force on CME Provider/Industry Collaboration, Pat Kelly, then president of Pfizer US, pointed out that the new conflict of interest rules would lead to the exclusion from CME “of those who, based on breadth and depth of experience, may be the best experts in science and industry. This then can only serve to restrict the free trade, or flow, of scientific and clinical information. And the ultimate losers in this scenario are the patients.”

But that’s like complaining about the weather—you can’t change it, you can only adjust to it. And adjusting is precisely what the companies represented by our panel are doing.

Yes, there is still value

The consensus of the experts we consulted was that despite all the obstacles, industry can still play a role in CME. As Hilary Schmidt, associate VP, medical education and medical communications, of Sanofi-Aventis explains: “Industry has as part of its mission to educate on the safe, effective, and appropriate use of therapies. Supporting education grants through CME is one approach that enables fair-balanced, evidence-based presentations and discussions of treatment options that are important to optimizing patient care. CME supported by industry should focus on closing important healthcare gaps that have been independently defined by credible authorities.”

Sepracor’s director, med ed, Ray Wolf gives a specific example of how a company can give grants to improve medical care in its areas of interest, as long as the programs are not related to specific products. He cites data that show “only 30% of primary care physicians utilize spirometry for the diagnosis of COPD.” Yet such testing is essential for the proper diagnosis and optimum care of patients with asthma. These data show the need for education, Wolf says, and that is why his company is committed to supporting it.

Another example is Pfizer’s awarding a record-breaking \$5 million grant to CEASE, an initiative designed to help doctors help their patients break their smoking habits. Formed by a nine-fold partnership that includes the California Academy of Family Physicians, the Interstate Postgraduate Medical Association and the

University of Wisconsin, CEASE has adopted guidelines for treating tobacco use and dependence developed by a consortium that includes the Centers for Disease Control and three National Health Institutes.

Pfizer’s Mike Saxton notes that smoking is the single most important preventable cause of death in the US and that the company, having long been interested in smoking suppression and marketing a product to suppress smoking, has done a lot of research in this field. “So are we funding programs around a product?” he asks. “No, absolutely not. But the biggest gap in healthcare performance that prevents patients from stopping smoking is the healthcare providers’ [lack of] competence in

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terms of their ability to counsel patients. Therefore, education designed to help healthcare providers improve their counseling ability is a rising tide that raises all ships.” Saxton, speaking several weeks before Pfizer’s policy shift, continues: “We don’t give grants that have no relation to our interests. Companies are not giving grants as charitable contributions. We are looking for the gap in healthcare performance in which the patients’ interests align with the healthcare providers’ interest, which also align with our own. We are looking for win-win-win situations.” Not only that, but he believes that the new ACCME standards actually encourage this model of grant-giving, “and I applaud the efforts of ACCME to raise the bar on quality,” he said.

This is also the rationale, Schmidt adds, why “Sanofi-Aventis currently supports education grants that are developed independently and in accord with ACCME criteria—and in improving healthcare providers’ knowledge, skills and performance in relation to specific healthcare gaps and educational needs.” Such thinking may, however, not be universally accepted in an industry focused on yearly or even quarterly results. Globally in the pharma industry there are not very many who understand the long-term value of education, Sepracor’s Wolf believes. “Moneys are becoming very, very tight,” he says, and people on the commercial side of industry want to see an immediate return on their investments, “but if you do an education program today you won’t necessarily get a return on that tomorrow. The new ACCME regulations raise the question why—if we can’t suggest topics and speakers—we should fund such education,” and explains why he has to “push upward” in order to get corporate funding.

The focus on outcome

Another challenge, as those we talked to overwhelmingly agree, is to improve the current system—to get away from the emphasis on credits and “butts in seats,” and instead to focus on outcome, aiming not just to improve learning and retention of information, but to demonstrate improvement in patient care. “That’s the only way we [the education people] can convince our funding groups, primarily our

commercial colleagues, that what we are doing has an impact,” says Wolf, which is why he will approve only those grant applications that include an extensive outcomes measure. It has, for instance, been suggested that CME providers set up control groups of doctors who do not participate in the program and compare their knowledge with that of the participants and then, if possible, to measure the difference in physician performance.

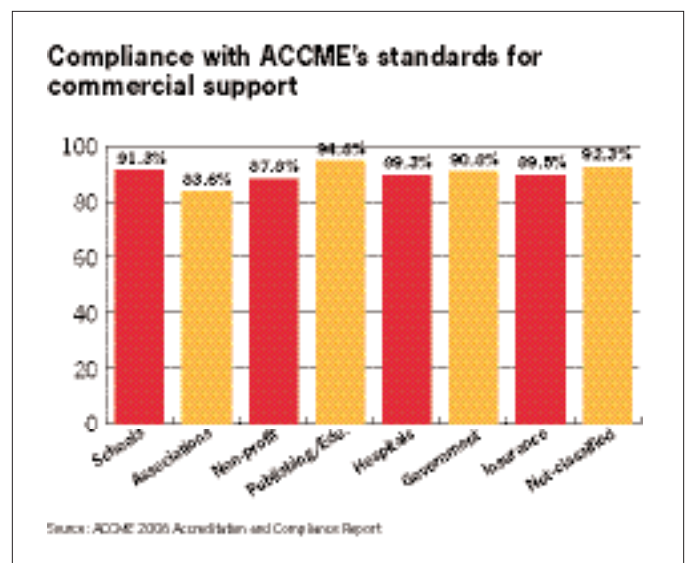
Jennifer Spear Smith, executive director, professional education services, Wyeth, would like to see three improvements:

- Fostering education focused on fixing actual gaps in care by moving from credit hours to competence and performance assessment;
- Increasing support of regional needs to better enable healthcare professionals to improve patient care; and
- “A requirement for healthcare professionals to be individually assessed, via means including but not limited to self-assessment, feedback, and chart pulls [so as to] enable their continuing professional development to be based on gaps in competencies that are required for the job.”

Obviously, education execs could not voice such policies without the support of upper echelon management, and Jeff Conklin, Wyeth’s VP for marketing practices and innovation, by way of example, explicitly confirmed that Smith’s views reflect company policy.

What’s noteworthy is that this emphasis on demonstrating the effectiveness of CME is in line with ACCME’s guidelines, which say that “outcomes measurements [are] more critical than ever,” and is also echoed by the Pharmaceutical Alliance for CME, which at its April 11 “summit” listed the highlighting of outcomes as one of its four areas of program emphasis.

Schlumber’s dream agenda includes multi-sponsorship of programs. It’s “absolutely the way to go,” he says, since it would spread the cost and thus, encourage manufacturers of second and third-rank products to participate, while Schmidt points out that it would also help to reduce the perception of industry bias. The second proposal on Schlumber’s list is that industry gather “real-life scenarios where CME has saved



people’s lives or made their lives better,” citing as an example the experience of Kevin Everett, the Buffalo Bills tight end, who sustained a life-threatening spine injury that might have kept him in a wheelchair all his life but who was able to walk again because his surgeon had happened to attend a CME program where he learned of a new technique for treating vertebral damage.

Quintiles’ Schlumper says he is looking for hard data to quantify the benefits of educational experience in place of the customary questionnaires. More controversially, he believes that industry should do a better job of assessing companies so as to “weed out those that are doing the dirty stuff that makes headlines.” And finally, adding to the consensus about outcomes, he would like to move “from the tally sheet mentality, where doctors feel if they spend this amount of time they get that amount of credit, to something a little more rational.”

The transparent way ahead

Lilly, saying it welcomes greater transparency in the healthcare system, has endorsed the Grassley bill and, along with Pfizer, has begun to post all educational grants online. AstraZeneca, according to Pamela Mason, director, medical education grants, is considering doing the same. Greater transparency she believes “would help to elevate the value of continuing medical education and improve the understanding of those outside the CME enterprise of the various roles of providers and supporters of CME.” But posting grants, which she endorses, is in Schmidt’s views only the beginning of how industry

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can improve transparency. “A company’s policies and decision-making processes for awarding grants should also be made very transparent,” she says, “since these are designed to help ensure compliance with all regulations and guidances, and promote integrity of all CME funded through grants.”

But shouldn’t the rules apply to others besides industry? Mason thinks so, saying that “in turn, it would be beneficial if educational providers, ACCME and other accrediting bodies began to explore how they can also be more transparent. Areas to consider include posting relevant information by the educational providers about funds received and activities conducted.”

Another suggestion for improving CME is for ACCME to conduct audits of what goes on in the field, rather than putting its emphasis on where the money comes from. Smith points out that “greater oversight by ACCME and other accrediting bodies would increase the level of competence of accredited providers, resulting in better independent education and fewer compliance issues.” She believes that increased collaboration among all types of providers would allow for synergies and economic efficiencies that could benefit the entire system.

Fixing the uneven playing field



What has long been the largest group of accredited providers, the for-profit medical education companies, is now being threatened by ACCME’s new one-sided rules to require firewalls to prevent commercial bias, firewalls that don’t apply to academic or medical society providers. In a recent publication issued by the North American Association of Medical Education and Communication Companies, Scott Gottlieb (above), a former FDA deputy commissioner, pointed out this inconsistency in ACCME’s attempt to prevent conflicts of interest. “The rules,” he said, “should apply to everyone – including academic providers. Just by virtue of the fact that they work in academia or a specialty society or hospital, they aren’t immune from the same kinds of potential influences and problems that may exist in a [medical education company]....”

But whoever said life was fair?

Not that there weren’t also minority opinions. One senior CME executive who preferred to remain anonymous suggested that if ACCME returned to its 1992 standards, which spelled out the responsibilities of CME providers, it could achieve its objectives of fairness and lack of bias without prohibiting industry participation. Others have floated the possibility of setting up a system for reviewing program content to assure accuracy and objectivity independent of ACCME. Such a plan would, of course, not entitle physicians to CME credit, but Mike Saxton, questioning the concept, observed that “no one cares about credit; that’s a minor issue. Independence is the issue.”

AstraZeneca’s Mason sees independence as the key to industry’s support of CME in the face of the difficult climate. Referring to AstraZeneca’s commitment to enhancing the health and well-being of people, she says that “one dimension of our commitment is supporting independent medical education because we believe that it can enhance patient care by providing healthcare professionals with the most current information on disease states, treatment options, and effective doctor-patient interaction.” The challenge will be to stretch budgets in order to support long-term quality improvement initiatives. “Although we face opportunities and challenges,” she says, “the prospects are exciting, and the results in quality improvement will be worth it.”

Pfizer’s Saxton is also optimistic about industry’s future participation, but stresses that it has to be done right and that it may not be easy. “What would improve the value of CME to industry and to providers is sequential, multi-faceted education that is more interactive and based on needs.” If those things are done and done well, he believes, industry will receive a higher return on its investment in education. That doesn’t mean, though, that industry will automatically provide more CME funding. In fact, there may be “a lot of bloodletting and a lot of change,” but ultimately, “when we turn that corner, it will be a win-win-win for everybody, and most important, for the patient.” ■

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