Dr. Ronald Vender, chief medical officer, Yale Medical Group; associate dean for clinical affairs, Yale School of Medicine

# BOLD SCHOOL

Academic medical centers are examining whether commercial support for CME should be allowed to continue and how to prevent bias if it does. As consensus builds, a hodgepodge of different policies threatens confusion. Could Yale's approach of allowing "principled" interactions become a national model? **Marc Iskowitz** reports

As more academic medical centers reassess their relations with industry, some are taking a hard line on commerically supported medical education. So far, restrictions on supported education have been piecemeal. For instance, while Harvard Medical School this year placed a ban on speakers' bureaus, or giving paid talks, the school doesn't have as strong a policy on continuing medical education (CME) as the University of Michigan Medical School, which is stopping all industry-funded CME.

Yale School of Medicine, which in September made mandatory its elective guidelines on industry interactions, opted for what it calls a "principled" approach. The policy, expanded from a set of 2005 guidelines, allows faculty to speak in CME courses or non-CME talks paid for by industry, and companies can support courses or lectures developed by the Yale faculty and CME office. However, financial entities cannot give input on topics, speakers or content. The rules are designed to ensure that faculty maintain complete control of content and are not perceived as hired guns.

"We rejected the idea that all interactions [with industry] are wrong and the notion that any relationship is a conflict of interest," says Dr. Ronald Vender, chief medical officer for the Yale Medical Group and associate dean for clinical affairs for the Yale School of Medicine. "[I]t's not that we are promoting interactions. But if one is going to have [them], we are promoting the concept of 'principled interactions.'"

In short, this means being dilligent in adhering to the rules—the Standards for Commercial Support from the Accreditation Council for Continuing Medical Education (ACCME) and Yale's own policies—whether the commercially supported education is delivered on campus or off, or is for credit or not. The university set up an enforcement mechanism.

**$3.26M**
**Average commercial support at an academic medical center in 2009, a 10.7% drop from 2008**

Yale's embrace of the principled way comes as major med ed policy makers near consensus on the funding issue. A national recommendation is due out in draft form early next year from the Conjoint Committee on CME (CCCME), a multi-stakeholder group.

## No evidence

The CCCME, formed in 2009 at the behest of the Institute of Medicine (IOM), appears to be close to endorsing an approach that relies on the ACCME standards, a set of rules for CME provider independence that manage potential bias and improper behavior by grantors. It's unlikely that the CCCME will declare commercial support problematic, according to Dr. Norman Kahn Jr., convener of the CCCME. A study commissioned by the ACCME in 2008 found that, "to date there is no empirical evidence to support or refute the hypothesis that [commericallly supported] CME activities are biased."

In fact, when the CCCME delved into the data and evidence, they

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found that what leads to bias is not commerical support on its own but the direct financial ties faculty often have with industry.

If the principled approach to maintaining commercial support argues on fact, the movement to end industry financing of CME is built largely on face. Just two years ago, the American Medical Association's Council on Ethical and Judicial Affairs (CEJA) called for an end to almost all commercial support for professional education—multiple times—and the ACCME had issued a call for comment to do the same. (CEJA's bids were rebuffed, each time, by AMA members, and the ACCME wound up calling off any ban.)

Two congressional committees investigated, Senate Finance starting in 2007 and Senate Aging in 2008. Since then, ACCME has developed faster and more public enforcement programs. But the argument that the ACCME Standards for Commercial Support offer adequate protection against commercial influence is still under attack.

Dr. Robert Jackler, associate dean for CME, Stanford University School of Medicine, argues that ACCME standards help but, with pharma and device funding, only courses in a company's financial interest are held, and topic selection is skewed toward diseases that require expensive therapies. Stanford has had a pooled approach for two years—in which commercial funds cannot be directed to a specific topic, speaker or activity but must be "designated" to one of four topic areas, and in-kind support like equipment and supplies can be designated to an activity. Pfizer is supplying a $3 million, three-year grant to fund areas of mutual interest.

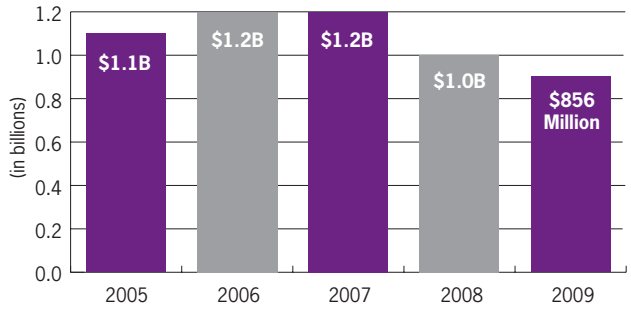
## An overdependence

Providers, by and large, are too dependent on commercial funding, says Maureen Doyle-Scharff, senior director, team lead, Pfizer Medical Education Group. She advocates the notion of supplemental funding (e.g., registration fees, pooled and block grants, non-pharma corporate donations) as a way to "restore the mindset that commercial support should not be the only thing" driving or funding an education program.

"We've lost our way, in a certain sense," she says, "because so much education is free, and it's just being dumped into the marketplace to the extent that CME, more or less, has become a commodity....It's more about collecting credit than about truly learning." That's not to say that industry grants are bad or create bias. "It just is a recognition of our reality and the perception [around] commercial support."

**Commercial support**

Industry dollars for CME slid 17% last year and 14% in 2008 following a peak in 2007.




Source: ACCME Annual Report

Proof of her position comes from the SACME/AAMC Harrison Survey, which shows that academic medical centers depended on industry funding for 49% of revenues last year. The average number of courses at an institution that would not have taken place without it—121.

But companies have already been curtailing grants, partly out of fear of regulatory attention, not to mention the recessionary state of the industry and the limited number of new products in the pipeline. Among all providers, grants now account for 39% of total CME income ($856 million), down from 56% ($1 billion) in 2008, according to ACCME's 2009 annual report.

**121** Average number of courses at an academic medical center that would not have taken place without commercial support last year

The pharmaceutical grant-making process "has become a very competitive process with very few grants awarded from the many applications received," reports Pamela Mason, director of the medical education grants office at AstraZeneca.

That means many other providers who depend on corporate financing are having to deal with less. This includes medical education companies, which saw a 21% drop last year. "We are not getting a resurgence of grant dollars until we can prove what CME can do in terms of changing physician behavior," says Dr. Dion Richetti, general manager of DIME, an accredited unit owned by Publicis Healthcare Communications Group (PHCG) that sponsors more than 100 activities a year. "Many grantors are now requiring that you demonstrate outcomes that support the value proposition for CME." One area DIME is focusing on is performance-improvement CME taking place within closed health systems.

In 2009 non-profit professional associations saw total commercial income fall nearly 25%, and other non-profits lost 35%. "We are looking around for other options to support meetings in addition to registration fees," says Dr. Rosemary Robertson, chief science officer of the American Heart Association (AHA). An overseas medical journal supported a small part of one meeting, and AHA has had to scale back amenities at its meetings while raising registration fees and soliciting federal grants from agencies like the CDC, NIH and AHRQ.

## Impact on outcomes

Has there been an impact on healthcare outcomes from reduced company support? According to ACCME data, the number of activities dropped 5.8% last year to 95,062 from 100,898 the year before, while hours of instruction fell 10.4% to 689,768 from 769,439 in 2008. The number of physician participants, meanwhile, increased 1% during that time to 10,780,093 (the figure is up 31% since 2006). CME requirements for licensure, though, have not changed, and many of the lost courses are being replaced, by and large, with enduring materials, particularly internet-based education.

Combine the decreases in hours and activities with the fact that physicians are getting more education online, and "that means there is less opportunity for them to, as part of their regular CME obligation, learn from colleagues and interact with faculty, and I think that can certainly impact the quality of the education that they are able to get," says Dr. Jack Kues, assistant dean for CME at the University of Cincinnati College of Medicine. "The jury may still be out on what kind of impact that may have on patient care,

## Restricted support

A handful of organizations are operating their CME programs with little or no commercial support (CS). Notably, most are affiliated with larger institutions able to contribute significantly to the med ed program.

**Baptist Health South Florida (Miami area, Broward & Monroe County)**

**CS prohibition:** September 2008
**How do they make it work:** The $2 million CME budget comes from central funds; exhibit fees accepted; auditoriums, classrooms and conference rooms available; in-kind support generally not accepted unless needed for workshops or live demos that could not otherwise be executed; unrestricted commercial grants accepted through foundation
**Supplemental sources:** Institutional support
**Courses:** Number targeted to external audiences same as before CS prohibition

**Brody School of Medicine at East Carolina University (Greenville, NC)**

**CS prohibition:** None
**How do they make it work:** Conducts a unified CME program with the non-profit Eastern AHEC; CS works out to be only about 1% of $650,000 CME budget with most coming from pharma; exhibit fees another 2.5%; no conference facility; some of Eastern AHEC's support is in-kind
**Supplemental sources:** Financial support and services from Eastern AHEC; registration fees; philanthropic grants; government contracts
**Courses:** Geared toward external primary care physicians, with some grand rounds

**Memorial Sloan-Kettering Cancer Center (New York, NY)**

**CS prohibition:** July 2006
**How do they make it work:** Basically, on learner fees; courses not promoted; fixed costs largely eliminated by using only full-time hospital employees as speakers and holding conferences either at MSKCC or co- or jointly sponsoring with another institution; marketing department can cover a shortfall; no in-kind support
**Supplemental sources:** Registration fees, institutional support
**Courses:** Number targeted to external audiences same

**Stanford University School of Medicine (Stanford, CA)**

**CS prohibition:** September 2008
**How they make it work:** Stanford accepts "designated" CS—it may not be directed for a particular program but flows into a central bucket; activities held on campus, and medical school pays administrative overhead and for those involved in maintaining ACCME accreditation; in-kind support OK
**Supplemental sources:** Two undesignated grants—one $3 million, three-year grant from Pfizer to fund education in mutually agreed upon areas, and a smaller one from Medtronic
**Courses:** Volume and attendance have remained relatively stable

**University of Michigan Medical School (Ann Arbor, MI)**


**CS prohibition:** June 2010
**How they make it work:** While the university has made a policy announcement through the media, implementation is still being worked out. It remains to be seen whether the dean will provide any institutional support to make up a $1.5 million shortfall
**Supplemental sources:** Registration fees
**Courses:** Too early to tell

but it's an important thing to watch."

Indeed, especially since two institutions have announced commercial support prohibitions. The University of Michigan made its policy announcement in June, through the media, to eliminate commercial financing for CME beginning in January. How the policy will be operationalized is still being worked out, but it is possible that with less money, there will be fewer CME courses available.

Memorial Sloan-Kettering Cancer Center eliminated industry funding from CME in 2006, and, according to Peter Brodhead, administrator of CME for the hospital: "The number of courses targeted to external audiences is the same" since then. "I don't believe that [removing] commercial support took anything away from the quality of our program."

Any lessons for others? "In our case, we were able to adopt this approach somewhat because of our internal assets," says Brodhead. These include a Manhattan conference center, full-time faculty contractually obligated to speak at CME events, and institutional support to make up budget shortfalls.

Not many providers have such resources. "If you're a medical school dean and have a medium-size CME program, you have to be willing to ask yourself, do I have a couple million dollars to put into the CME program that I don't need somewhere else?" says Kues.

### A matter of principle

Because it's such a big part of their revenue, most medical schools want to understand the implications before they stop accepting industry funds. And most are probably waiting for a national recommendation before making a move. The CCCME, which has 16 member organizations behind it, is working on one.

"Our charge is not to skip straight to a specific strategy [that] is to avoid commercial support," says CCCME's Kahn, who is also EVP and CEO, Council of Medical Specialty Societies (CMSS). "It is unlikely that we will make such a recommendation."

Kahn says it would be good if overarching recommendations from the Association of American Medical Colleges (AAMC) were implemented. The AAMC position can be summed up in a 2008 report from the AAMC Task Force on Industry Funding of Medical Education: "In their educational interactions, academic medical institutions and industry are mutually accountable for maintaining a principled partnership based on the primary goal of providing the highest quality of care for patients."

Dr. Dave Davis, AAMC's VP for continuing healthcare education and improvement, adds: "The AAMC policy on commercial support spells out the reservations we have about an overabundance of commercial support and sides with the [ACCME] that says we need to be very, very clear about the bright line of promotional aspects vs. education. Using those standards as a tool is a very useful thing."

The data are "incontrovertible" that direct financial payments lead to influence, but a commercially supported CME activity whose faculty have no such ties most likely does not lead to bias, Kahn explains. "[W]ithin the context of the firewalls created by the ACCME's Standards for Commercial Support, it's the opinion of the profession that if you follow this framework, you can eliminate influence from commercial support."

And how did the CCCME reach its conclusion? Explains Kahn: "That's what happens when you start looking at the data and evidence and you get over your preconceptions and biases." ■