The Medical School will decline industry funding for continuing medical education even before a major report opines on corporate influence and conflict of interest.

BY JEFF MORTIMER

Medical School Dean James Woolliscroft's misgivings about industry's ties to medical education have deep roots.

"Even when I was a resident," he recalls, "I vividly remember faculty members on the speakers circuit who would give lectures or presentations with a drug company's logo prominently displayed, and wondering how much that influenced their recommendation for a certain antibiotic or anti-hypertensive. Drug companies are strategic. They identify the educationally pivotal people to maximize their influence, people who can say, 'You prescribe drug X when you do this.' How many hundreds of residents and medical students are you going to influence this way?"

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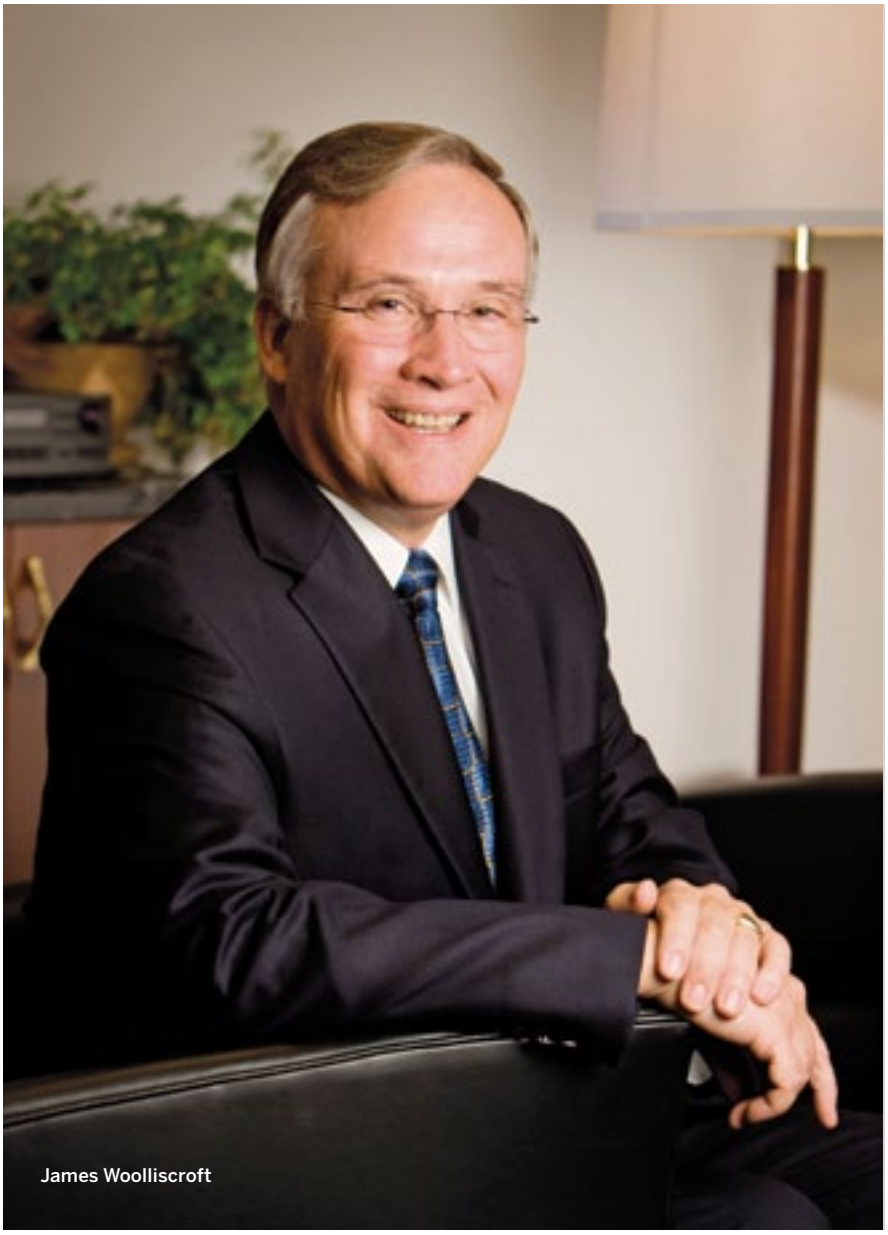
Or, in the case of continuing medical education, how many practicing physicians? As executive associate dean, Woolliscroft chaired the committee that standardized the Medical School's management of conflict of interest in research. After he became interim dean, he increasingly understood "that conflict of interest went way beyond research, into essentially all of our missions."

The Medical School's involvement in CME, in various forms and under a variety of names, goes back nearly to its founding. The school had begun inviting community physicians to bring in their most difficult cases in the 1860s. The precursor to today's Office of Continuing Medical Education, now part of the Department of Medical Education, was founded in 1927. When it opened in 1969, the U-M Towsley Center was the first building in the country dedicated to community medical education.

Spurred by increases in the amount of postgraduate study required of physicians in order to retain their licenses, CME grew steadily into the 1990s. And then, spurred by industry spending, it exploded. From 1998 to 2006, the number of CME activities nationally almost doubled. During that same period, corporate support for CME more than tripled, eventually accounting for 61 percent of all CME funding.



James Woolliscroft

The introduction of blockbuster drugs like Lipitor and Viagra and pricey procedures like hip and knee replacements had spawned a financial bonanza for the health care industry. What better way to reinvest the profits from those products than in marketing to the only people who were legally entitled to use them, especially since they were obliged to take CME courses anyway?

Industry's ways of influencing physicians' decisions also included speakers' bureaus, consultancies, junkets, opulent exhibits at medical conventions, and outright gifts. The effects of such seismic changes in the landscape did not go unnoticed. Anecdotes abounded about what looked like attempts to compromise physicians' integrity. Articles and books were published, documentaries produced, congressional hearings called.

In 2003, the Office of Inspector General of the U.S. Department of Health and Human Services issued guidance to the pharmaceutical industry detailing which practices were acceptable and which constituted fraud. A year later, the Accreditation Council for Continuing Medical Education published its Standards for Commercial Support in order to "ensure the independence of CME activities."

MARTIN VLOET, U-M PHOTO SERVICES

Van Harrison, Ph.D., professor of medical education, directed the Medical School's Continuing Medical Education Office from 1983 to 2009. He is widely recognized for his leadership and expertise in the field, and he thinks the steps taken by HHS and ACCME successfully addressed abuses.

"Reviews of existing literature have found no evidence of systematic bias in independently developed CME activities that receive commercial support," he says. "People who argue against accepting commercial support for CME generally focus on a potential for influence and do not believe that any rules can adequately mitigate that potential. Often anecdotes from before the stricter rules were implemented are used to provoke an emotional decision on the issue. Net benefits and harms to patients are seldom addressed."

Harrison sees several drawbacks to refusing industry support at this time, chiefly a likely reduction by a quarter to a half in the number of CME activities for community physicians offered by the Medical School, which has long been the state's leading CME provider. His concern is that those physicians' patients may suffer as a result. Additionally, patients they might have referred to the U-M for clinical care or research may go instead to other institutions. Most CME providers are waiting for the report, due next spring, of the Conjoint Committee for CME, which is being coordinated by the Council of Medical Specialty Societies.

"Virtually nobody is moving — they're waiting to see what this report recommends," Harrison says. "If you change now and the report says little change is needed, you've cut yourself out of a major funding resource to offer CME. Leadership understood we would take a 'hit' by going without the money when other people have it, and has taken a position that they hope will lead the country and a meaningful risk that it will not."

The Medical School took action when it did, says Woolliscroft, because, "The archives are filled with erudite volumes that have been put together by expert committees and haven't made a whit of difference. It's a little different when a school or college comes together and says this is where we're going, because then you actually do something. In areas where we can have direct impact and leadership, we should do so."

It was Woolliscroft's concern as dean about conflict of interest that led to the formation of the committee that Paul Lichter (M.D. 1964, Residency 1968) chaired.

Lichter has been chair of the Department of Ophthalmology and Visual Sciences since 1978. He, too, has a long history of involvement in this issue, in part because his department has never accepted corporate support for CME. While the Medical School has a standing Conflict of Interest Board, its focus is on research and technology transfer. Woolliscroft wanted a panel that would investigate, in Lichter's words, "how industry can influence decisions physicians make in general, and where the Medical School felt the line should be drawn."

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Lichter felt strongly that this panel be made up largely of departmental chairs. "It was my thought that ultimately we would be making policy recommendations that would go to the chairs, so we would be better served to populate the committee with many chairs," says Lichter. "If they didn't agree with something, we might as well find out sooner than later."

Called the Clinical Conflict of Interest Group, Lichter and colleagues used a 2008 report by an Association of American Medical Colleges' (AAMC) task force on industry funding of medical education as a template. It finished working on CME first and, at the dean's request, sent its recommendation to him rather than waiting to complete all its deliberations on medical education issues. He, in turn, presented it to the Dean's Advisory Committee, comprised of the chairs of all the Medical School's departments, including the Department of Medical Education, who approved it unanimously.

Lichter doesn't agree with the contention that doctors are immune to being biased by corporate support.

"It's now well known through functional magnetic resonance imaging studies that bias is a hard-wired process in our brains," he says. "When we are given something, there is a part of our brain that responds in a way that is very biased toward reciprocity. When we receive money from a pharmaceutical or device company, we would be inclined to favor products of that company. Whether the company tells us to talk about a specific product or not doesn't matter."

There's also a factual basis for believing that the current arrangement is bad for patients, he says: "Every dollar that

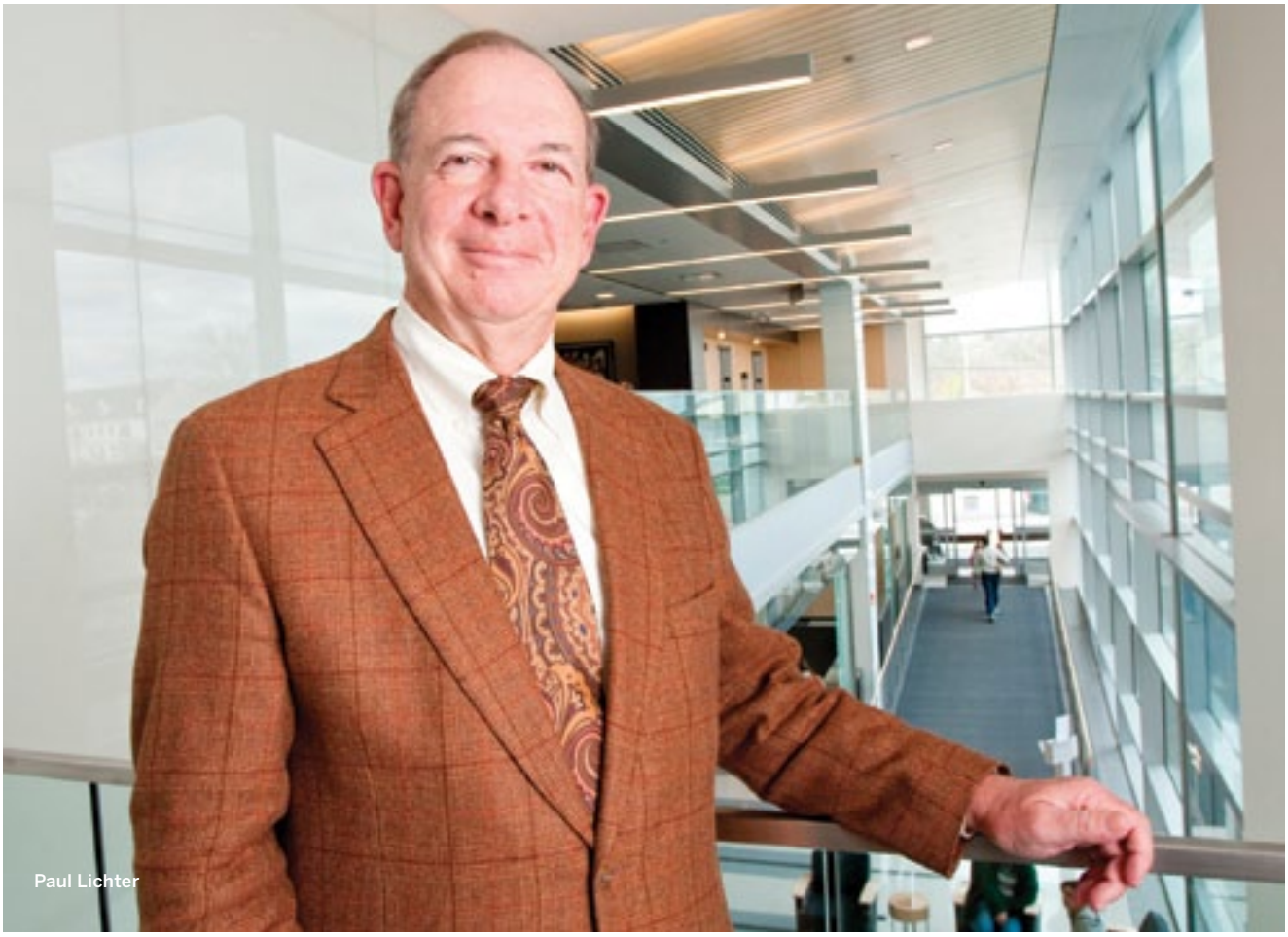
industry spends on marketing goes into the price of drugs and devices. This means that patients pay for it. How is that helping doctors help patients? Industry's CME support also leads to the increased use of expensive drugs and devices, many of which are not proven to help patients."

Helping patients is the litmus test, and some relationships between medicine and industry pass it. "When we get a new instrument in the OR, for instance, often part of the contract is that the company teaches the surgeons and residents how to use it," says Woolliscroft. "Occasionally, there's CME around that. We said, that's only appropriate. You don't want them learning new technology or devices on our patients."

And there's no way around collaborating with industry on research. "The way they develop drugs and devices, by necessity, has to involve physicians," says Lichter. "One could call it an unholy alliance but, whatever it is, it can help the public in the end. But while it's the physician's role to work with companies to develop drugs and devices that are in the public's interest, it isn't the physician's role to sell the drugs and devices for companies."

No one is more aware of that distinction than Raymond J. Hutchinson, M.D., associate dean for regulatory affairs and chair of the Conflict of Interest Board, who served on the AAMC committee that produced a recent report on conflict of interest in clinical care.

"I refused to take a black bag when I got my degree at Dartmouth in 1970 because I felt it wasn't the proper thing to do," he says. "I don't get involved in industry ties in order to avoid concerns about my patient care, my resident education, or my personal behaviors. I think it's a good idea to maintain some distance, but we live in the real world, too. We do have to interface with medical industries to further the interests of our patients, particularly on the research side. I think on the CME front, if we can, it's best to deliver the education free of industrial or biomedical industrial influence, or the appearance of influence."



Paul Lichter

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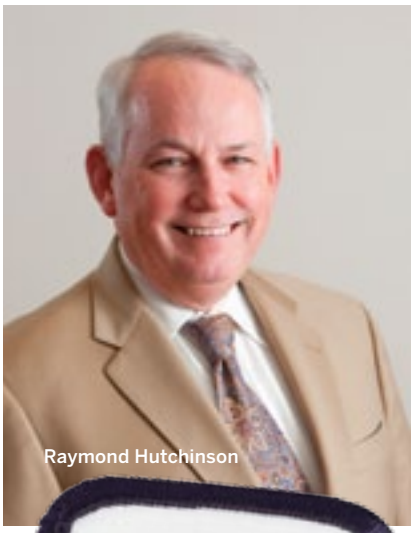
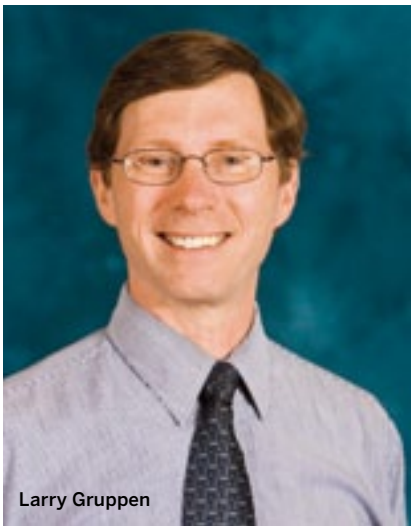
Van Harrison


Raymond Hutchinson


Larry Gruppen

If the spike in industry money for CME in the late 1990s and early 2000s created a "new normal," how much of it will still be delivered under the terms of what Woolliscroft calls the "new, new normal," and in what forms?

"It's not as if the practicing physician will now suddenly be unable to find CME activities," says Larry Gruppen, Ph.D., chair of the Department of Medical Education and acting director of the Office of CME. "Getting the number of credits you need for maintaining your license is not at all difficult. You can get them for an array of activities: reading, audio tapes, self-study in journals, online, podcasts ... "

"That's where continuing education is moving very, very rapidly," says Woolliscroft. "What we do now, the sage-on-the-stage sort of thing, will no longer be relevant. Arguably, it's not relevant now."

Besides, industry support is shrinking along with its revenue bubble. The recession, profitable drugs coming off patent, and an ongoing lack of new blockbusters to replace them have all dampened enthusiasm for lavish marketing endeavors.

But Woolliscroft admits that still leaves some financial holes to be filled. "We're trying to figure out what are the really key reasons we're doing CME," he says. "Which of the courses really meet the criteria? Those are the ones that we need to continue. How do we do that? In some cases, the departments or divisions are stepping up and funding them. In several cases, the cost of putting on the course is being decreased. Rather than a nice resort up north, we can have it here or at an area hotel, which lowers the expenses."

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Participant fees could also be increased, but that raises what Hutchinson calls one of the "valid points the minority makes that have to be considered in this process." Not all CME participants are doctors, and the ones who aren't — nurses and ancillary personnel, for example — could be priced out of the market.

But if there are devils in the details, there may also be an angel in the big picture.

"The controversy has been around what impact the courses may have had on physician behavior," says Gruppen, "but to me what's equally salient is that money had a strong biasing impact on what topics were presented. Many issues that are important but not money-makers got little attention because there was no outside commercial support for them. When we free ourselves from that, we'll have a lot more flexibility."

CME content that is driven by therapeutic needs rather than industry's marketing agenda would seem to be an undoubted boon to patients, but there's still at least one devil that's left to confront.

"The wonderful idea of socially responsible CME courses will depend to a considerable degree," Gruppen says, "on whether somebody is willing to pay for it." [M]