

CME, PHYSICIANS, AND PAVLOV: CAN WE CHANGE WHAT HAPPENS WHEN INDUSTRY RINGS THE BELL?

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ABSTRACT

Purpose: To show how physicians' conditioned response to "keeping up" has helped industry's opportunistic funding of continuing medical education (CME) and to propose ways to counter the conditioned response to the benefit of patients and the public.

Methods: Review of the literature and commentary on it.

Results: The pharmaceutical and device industries (hereafter referred to as *industry*) have a long history of bribing physicians to prescribe and use their products. Increasing pressure from Congress and the public has been brought to bear on industry gifting. This pressure, coinciding with increasing financial problems for the providers of CME, provided industry with reason and opportunity to expand its role in the financing of CME. Industry's incentive to make its CME funding appear to be an arm's-length transaction has spawned medical education service supplier (MESS) companies. Industry makes "unrestricted grants" to the MESS, and the MESS puts on the CME program. Helped by these CME programs, industry is able to subtly "buy" physicians one at a time, so that under the cover of "education" they and their academic institutions and medical organizations lose sight of being CME pawns in industry's sole objective: profit.

Conclusions: Despite a vast literature showing how physician integrity is easy prey to industry, the medical profession continues to allow industry to have a detrimental influence on the practice of medicine and on physician respectability. It will take resolute action to change the medical profession's conditioned response to industry's CME bell and its negative effect on patients and the public.

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INTRODUCTION

"The traditional independence of physicians and the welfare of the public are being threatened by the new vogue among drug manufacturers to promote their products by assuming an aggressive role in the 'education' of doctors."¹ Although written nearly a half-century ago, this comment is worth considering today, especially as it pertains to continuing medical education (CME).

We commonly invoke CME to mean something good and something needed. In many ways we seem to respond to it with a conditioned, Pavlovian, response. CME helps assure us and our patients that we are up to date in a fast-changing medical environment. The number of CME offerings grows annually. Yet, while it grows, much has transpired in the field of CME to turn it on its head. Physician-industry relationships in CME have led to a creeping skepticism about how CME is planned and financed. Questions being asked about the teachers, their sponsors, and their objectivity are taking a toll on physician credibility. How did this happen? What is fueling it? Perhaps CME's physician participants and teachers have lost their way. If so, what can be done to restore them to their former respectability?

CME'S BEGINNINGS

The first attempt at CME in the United States has been attributed to the first president of the Massachusetts Medical Society, John Warren, who, in 1782, developed an organized program to train surgeons better.² Mostly, though, the earliest efforts at CME were simply physicians getting together on their own at doctors' dining clubs "to exchange ideas, introduce new methods and instruments, and keep abreast of developments over a broad spectrum of medical practice."³ The first of these clubs was formed in 1735 in Boston. In 1760, one was founded in New Brunswick, New Jersey, that evolved into the New Jersey State Medical Society. Doctors' dining clubs exist to this day—the Detroit Ophthalmological Club, in which the author is a member, being one—even though their need as an educational vehicle has long since passed. Large cities developed their own postgraduate education programs, among the first of which was a program in New York City that, in 1924, culminated in the New York Academy of Medicine.²

The inferior state of medical education in the United States in the early 20th century and its highly commercial flavor led the Carnegie Foundation for the Advancement of Teaching to commission what became known as the Flexner Report.⁴ This tour de force report is credited with transforming medical education from a disorganized, underfunded, largely inferior collection of many medical schools into a considerably smaller set of schools with qualified faculty, well-equipped laboratories, and teaching hospitals wherein a high level of education was delivered. The Report reviewed postgraduate medical programs—largely the foundations of today's residency programs—and found very few of acceptable quality. As a result of Flexner's study and report, postgraduate training took on a more formal approach and specialties developed certification programs. The American Board of Ophthalmology (ABO) was established as the first specialty board in 1916.

Much of what was initially termed postgraduate medical education was actually remedial, provided simply to train a medical school graduate to actually be able to practice medicine. Education after internship and residency was quite inadequate in most fields

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of medicine in the first quarter of the 20th century. In 1927, the University of Michigan formed the country's first Department of Postgraduate Medicine, and thus began the gradual divide between graduate medical education and CME.⁵ It would take another 20 years before this distinction received permanence and respectability. Shepherd⁶ considered 1947 to be a pivotal year in continuing medical education, as in that year the constitution of the newly formed American Academy of Family Practice required that each of its members obtain at least 50 hours of formal postgraduate education and 100 hours of informal education every 3 years in order to maintain membership. This mandate was critical in encouraging other societies, including the American Medical Association (AMA), to adopt CME standards, although the process took many years to become widespread.

EVOLUTION OF THE CME INDUSTRY

In 1950, there were 1,566 postgraduate courses in the United States, and their total attendance was 402,020.⁶ Offerings of CME programs continued to grow. Some physicians wondered why. As Miller⁷ said in a talk in 1974, "Having been convinced that 'keeping up' is the goal, we are then easily led to the conclusion that the need in continuing education is for more instruction: for example, 3,677 accredited courses were offered in the 1974-1975 academic year, compared to less than half that number 10 years earlier." The notion that more CME is needed persists to this day. The astounding increase in the number of CME offerings can be seen in the Accreditation Council for Continuing Medical Education's (ACCME's) 2006 Annual Report: 41,898 accredited CME courses plus another 51,684 accredited CME offerings of other types for a total of 93,582 accredited CME offerings in 2006. Contrast that with the total number of accredited CME offerings in 1998 of 48,092.⁸ While the burgeoning of CME from 1950 to today is astonishing, it is all the more remarkable that the number of CME offerings nearly doubled between 1998 and 2006. Is all of this CME needed? The cause of the rapid expansion in CME may be related to who is paying for it as well as to continually increasing requirements to obtain it.

CME ACCREDITATION AND MANDATES

In 1957, the AMA published "A Guide Regarding Objectives and Basic Principles of Postgraduate Medical Education Programs," which included a recommendation to publish in *JAMA* only those courses that met criteria to make them acceptable programs.⁶ This was the forerunner of the ACCME's accreditation program. The ACCME was formed in 1981 on the AMA's initiative and currently includes 7 representative organizations: AMA, American Board of Medical Specialties (ABMS), American Hospital Association, Association for Hospital Medical Education, Association of American Medical Colleges, Council of Medical Specialty Societies, and Federation of State Medical Boards. Some 729 entities were accredited in 2006⁸ to offer national CME, and 2500 could provide accredited local programs.⁹ Imagine the number of speakers needed each year to teach in the programs offered by all of these accredited CME purveyors.

To stimulate physicians to remain current with advances in medicine, the AMA launched the Physician's Recognition Award (PRA).¹⁰ The Award, now in its 40th year, provides documentation that a physician took the requisite amount of CME during the year. The AMA PRA is recognized by 33 states as fulfilling the CME requirements of their state medical boards. In 1972, New Mexico enacted the first state law requiring CME,⁵ and other states have followed suit, although, surprisingly, one-third of the states have no such law. Some state medical societies have a CME requirement for membership, the first to have enacted this rule being Oregon and Pennsylvania in 1970.

In terms of leadership in CME, the AMA has been at the forefront since the beginning. In addition to its having initiated the ACCME and the PRA, the AMA has conducted numerous conferences and workshops, has maintained a national CME database, and has promoted the importance of CME on an ongoing basis.¹¹ Interestingly, while the notion of required CME was first raised in a 1932 report from the Commission on Medical Education,¹² and while the first actual requirement for CME was mandated by the American Board of Urology in 1934,¹³ it was not until much later—1947—that CME requirements began to take hold.⁶ This was centuries later than the first public record of compulsory CME in Venice, Italy.¹⁴ In any event, what began as a modest endeavor to help physicians keep up evolved into a rather vast industry, at least in part as a response to the rapid expansion of licensing and accreditation requirements. All of this costs money, and lots of it.

WHO PAYS FOR CME?

In the 1950s, CME programs were disorganized, were not taught well, and faced problems of cost.¹⁵ The cost of CME has been a recurring theme for physicians, but, interestingly, it was not entirely the cost of the CME itself that mattered most. Rather, in a 1980 AMA survey, it was lost practice income while attending a CME course that physicians cited as the most costly part of CME.¹⁶ In the same survey, as in a similar survey in 1955, 84% of physicians believed that they themselves should fund their own CME.

Things are much different today. The costs to organize and conduct CME programs provided an opportunity for commercial enterprises to step in and help. As support by the pharmaceutical and device industry has taken hold, physicians have come to expect to pay neither the full cost of CME itself nor the full cost of meals and snacks that accompany the CME event. A report of academic medicine's CME activities that includes sources of funding shows that industry support has increased substantially over the years.¹⁷ For example, in 1986-1987, only 15% of the 40 medical schools taking part in the survey received over 40% of CME financial support from industry. However, in 2004-2005—just 18 years later—that level of industry financial support for CME was reported by 64% of the 55 medical schools returning the survey questionnaire. What this shows is how dependent academic medical centers have become on industry's financial underpinnings to make their CME programs viable. That trend suits industry's interests. The more that CME programs depend on industry for their support, the more industry can influence them and influence the speakers who teach in the

programs. While industry's CME support grew, coincidentally so did its need to make its marketing to physicians less overt.

INDUSTRY ADAPTS ITS GIFT-GIVING APPROACH

In fact, industry has changed its pattern of "gifting" to physicians over the past several years. Fearing Congressional action to limit its marketing activities, industry developed guidelines to placate Congress. The PhRMA Code¹⁸ still allowed a wide berth for companies to "bribe" physicians to prescribe expensive drugs and purchase expensive devices even as it put some conditions on what can be done. Around the same time, the US Office of the Inspector General issued its own guidelines regarding industry gift giving,¹⁹ also putting a damper on the ways in which industry could give money to physicians. These events, coincidental or otherwise, seem to be associated with industry moving even more of its money to market to physicians in the CME arena, where it is easier to operate. This trend accounts for the 40% increase in total CME offerings between the years 2003 and 2006.⁸ What's more, CME physician faculty have learned that commercially funded CME programs pay higher honoraria than do those run by a medical school. This is driving faculty toward wanting to teach in industry-funded CME programs and making it more difficult to produce academic CME programs without substantial commercial funding.⁹ Because industry-funded CME programs cover topics that are perceived as "new" by physician attendees, they prefer those programs to ones with topics that present older material—important as those topics may be to medical practice.⁹ According to Harrison,⁹ ". . . the artificially increased number of courses addressing a topic related to a product can inflate physicians' perceptions of the importance of the topic." This is simply another way in which industry-funded CME can influence medical practice. Ultimately, this strategy serves the companies while it leads to increased health care costs to the detriment of patients and the public.

Physicians develop a sense of entitlement that begins in medical school that helps explain why they expect and are eager to accept industry's largesse.²⁰ What is more, because much of the money actually going to physicians is hidden through "unrestricted grants," physicians are unaware of the extent to which industry funds their CME. Certainly, physicians don't realize that industry considers these dollars as marketing costs and tacks them on to the costs of drugs and devices—for which their patients pay.⁹ Physician organizations and state medical societies receive 30% to 51% of their CME revenue through industry, and they make a profit on the CME they provide. It is not surprising that these organizations are reluctant to place restrictions on commercial funding of CME.⁹

THE EXPANSION OF CME AND INDUSTRY'S INVOLVEMENT

In a 1987 overview of the CME enterprise, Felch²¹ commented on the spiraling costs of CME—which he estimated at more than \$10 billion annually—but pointed out that many believed that physicians, as the main buyers of CME, would control need and quality by simply not purchasing inferior offerings. Has that belief been confirmed? It appears not.

Peering at the future of CME from a 1991 vantage point, Bellande²² mentioned 6 reasons why CME would expand greatly in the years ahead: requirements for specialty board recertification first begun by Family Practice in 1969; proliferation of medical information, including new technology; state licensing board CME requirements; standard-of-care issues; outcomes assessment; and utilization review. All of these activities include an element of continued learning, and as Bellande predicted, there has been a vast proliferation of CME programs to deal with them. Has this been beneficial? Bellande pointed out that costs of CME were driving changes and that he expected increasing industry support of CME programs to reduce physician costs of attendance. Again, he predicted correctly. He also discussed how Congress, through Senator Edward Kennedy's Labor and Human Resources Committee, had been investigating industry involvement in CME and finding that those industry expenditures were unnecessarily driving up the costs of health care. These congressional concerns, as well as resultant guidelines from the profession,²³ from the ACCME,²⁴ and from industry,¹⁸ eventually spawned the medical education service supplier (MESS) industry.^{13, 25}

MEDICAL EDUCATION SERVICE SUPPLIERS

The MESS companies have provided the mechanism whereby industry does not appear to be funding a CME activity directly. Rather, a company gives the MESS an "unrestricted grant" to arrange and pay for the CME offering. According to the 2006 ACCME Annual Report,⁸ industry supported 61% of CME expenses nationally. Much of this money came through the MESS unrestricted-grant-from-industry route and, therefore, may not seem as obvious to attendees or instructors as coming from industry. In 2007, the ACCME revised its policies on accreditation to make it more difficult for industry to have a say in who speaks and what is taught in courses organized through a MESS. However, when the MESS knows where its next contract and check will come from, it is difficult to imagine that industry will not get its money's worth. As long as these suppliers can be accredited to deliver CME programs, industry will have an influence on what is presented and by whom. Is this in the interest of the public and of physicians?

In a review of a survey of MESSs, Ross and associates²⁶ took a hard line on involvement of industry or MESSs in accredited CME activities: "A for-profit, pharmaceutical industry-oriented company is a poor candidate for organizing physician education as there is a clear conflict between the needs of MESSs' clients and stockholders and the need for unbiased information in physician education. . . . The quality of graduate medical education must be assured. Both resident and physician education are too important to be provided by a biased source such as a pharmaceutical manufacturer or a MESS acting on its behalf."

STOKING PHYSICIANS' CME INSTINCTS

Physicians' interest in keeping up can arguably be traced to Hippocrates.¹³ Because it is a conditioned response for physicians, their learning radar is sensitive to hearing about the latest development, be it a disease, a drug, or a device—anything they can incorporate into their practices. Physicians do not want to be outdated and thus are vulnerable to a pitch about something new. The pharmaceutical

and device industries live off of “something new.” Never mind whether it is an advance or not. As long as industry can make it appear “new,” then industry can have its physician speakers bureau and key opinion leaders tout it. Instinctively, as stated earlier, physician audiences will want to hear about it and can often be swayed to prescribe or purchase the “new” drug or device, all under the CME umbrella. As May said in 1961, “. . . the doctor is made to feel he needs more ‘education’ because of the prolific outpouring of strange brands but not really new drugs, produced for profit rather than to fill an essential purpose; and then the promoter offers to rescue him from confusion by a corresponding brand of ‘education.’”¹

WHAT CAN BE DONE?

Commercial funding of CME has gone through the roof. It doesn’t take a study to realize that this funding has created much more CME than is needed to satisfy the purpose of CME—namely, as the AMA’s tagline says, “Helping doctors help patients.” Physicians want to keep up, they want to maintain their certifications and memberships, and some want to be teachers to help their colleagues achieve those goals. What has gone wrong, though, in this very worthwhile endeavor is that industry has taken over CME—for commercial rather than professional purposes. And we physicians have allowed this to happen, perhaps without realizing what it means.²⁷ Since industry spends its money only to increase shareholder value, the money it spends on CME is not given with the intent of helping doctors help patients. It’s given to sell more drugs and more devices.²⁵ Yet that straightforward fact is difficult for physicians to grasp. Industry tells physicians that they are too smart to be influenced by a free meal, and we believe them. Industry tells its speakers bureau physicians that they can talk about whatever they’d like and, of course, that the honorarium can’t influence such a smart doctor. If we physicians are so smart about industry’s tactics, then industry must be wasting much of the billions of dollars it spends on marketing to us—CME funding being part of the overall approach.

If we physicians are so smart, we would realize that industry is not wasting its marketing money. And we would realize that when industry spends a dollar on marketing, this money goes into the price of drugs and devices. That means that our patients pay for it. That means that we all pay for it. How is that helping doctors help patients? If industry’s CME marketing costs were the only extra burden placed on the health care system, it would be bad enough. But industry’s CME support leads to the increased use of expensive drugs and devices, many of which are unproven to help patients.

CHANGING THE PICTURE

Before we can change this picture, we need to recognize the picture. It may well be that individual physicians will have a harder time making changes than physician member societies and academic medical centers.

Among the changes that can be considered to counter the influence of industry on CME is to simply not allow it.

1. Physicians could refuse to attend CME offerings that are funded by industry—either directly or through MESSs and indirect grants.
2. Physicians could pay for the full cost of their continuing education, just like lawyers, accountants, and business people do.
3. Physician teachers could refuse to accept invitations to teach in CME offerings that are funded by industry money—no matter how the money is laundered.
4. Academic medical centers could refuse to accept industry support for any of its CME activities, just like Sloan-Kettering did last year.²⁸ Their faculty could refuse invitations to be on speakers bureaus or to have frivolous consulting positions. Their leaders could avoid institutional conflicts of interest that can give industry undue influence.²⁹⁻³¹
5. Physician member organizations could set a goal to be free of industry support for CME and begin to wean themselves of industry funding.

All of these measures would not only lead to better CME, educationally independent and geared to helping doctors help their patients, but the measures would result in a reduction in the plethora of CME offerings. There would be no opportunity for industry to use CME to help weave its web of improper influences on the practice of medicine. As May indicated in 1961,¹ these changes are not easy: “. . . unfortunately the best intentions of any group are liable to serious dislocation by the machinations of some eager specialists in promotion who may be oblivious to anything but personal gain.”

EXAMPLE OF A VIRTUOUS ORGANIZATION

Among physician member organizations, the American Ophthalmological Society (AOS) is notable by its refusal to solicit or accept industry funding of any kind. The members pay dues and pay for the yearly meeting they attend—all travel and expenses included. The AOS has been around since 1864 and its funding system seems to work. It can work for other organizations, too, if the membership has the will. The recent Macy conference concluded that there is no place for industry in supporting continuing education for physicians.³² When industry rings its CME bell, can we train ourselves not to respond?

CONCLUSION

The fact that the issues we talk about today have been around “forever” and that large majorities of well-intentioned practitioners can be foiled in their ethical intentions by only a relative few serves to emphasize how difficult it will be to achieve the changes suggested here. Nevertheless, the almost daily revelations in the press and in the literature about physician-industry conflicts of interest make our time appear different than in 1961, when May asked: “Do all concerned realize the hazard of arousing the wrath of the people by an unwholesome entanglement of doctors with the makers and sellers of drugs?”¹ Has that time arrived?

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PEER DISCUSSION

DR. JAYNE S. WEISS: The encroachment of industry on the practice of ophthalmology is underscored by the statistics just presented. The premise that industry has a vested interest in providing educational vehicles for physicians is irrefutable. Nevertheless, the solution proposed deserves more scrutiny. Can we indeed turn the clock back to those times of virtue when industry conflicts were minimal or non-existent? Is such a notion even possible in the current day and age?

Most importantly, if credibility is adversely impacted by industry ties, why do institutions, medical schools and doctors continue to accept industry dollars? While greed may be the driving force for some, the causes are more complex for the majority. The opportunity for industry's largess is being created by the dearth of alternative funding sources to pay the costs of institutions and educational programs. Financial streams are drying up and industry has the fix because their dollars can make up for budgetary shortfalls.

Sloan Kettering is held up as an example of virtue because this institution courageously has chosen to refuse industry funding. However, in 2006, the New York Times reported that Sloan Kettering had an endowment of almost 2 billion dollars.² How many institutions are fortunate enough to boast a monetary foundation close to this amount? Certainly not those that are financially struggling. Sloan Kettering is in the enviable position of having sufficient financial backing to be able to take the high road. Those institutions that are poorly funded and do not have the cushion of such a substantial endowment, may be equally virtuous but just financially unable to follow suit.

What about the individual physician? While some physicians may develop the sense of entitlement in medical school described by Dr. Lichter, these same physicians may also develop a sense of panic related to their increasing educational debt. Medical school loans have been increasing at a faster rate than inflation with the average medical student graduating with \$139,000 in debt; a 6.9% increase over the prior year.³

At the same time that the cost of medical care has increased, federal research funding and insurance reimbursements for patient care have continued their downward spiral. From 1993 to 2006, Medicare payments for cataract surgery were cut by 42% in real dollars (Personal correspondence William L. Rich III MD, FACS, AAO Medical Director of Health Policy, May 1, 2008)) The future looks even more bleak. President Bush's fiscal 2009 budget proposal includes an additional 200 billion dollars of Medicaid Medicare cuts.⁴

The decrease in patient reimbursement has impact on physicians in all practice settings. Academic physicians are increasingly urged to be more financially productive, which translates to spending more hours in patient care and generating revenue. While the traditional academic pursuits of writing research papers and giving talks do not generate income to pay the travel expenses for the out of town professional conference, a speaker's fee can. Is entitlement of doctors fueling their willingness to facilitate industry's message, or for some is it a more basic issue of practical finances?

The frequency of these potential conflicts appears consistent among disparate groups. The author observes that financial conflicts were reported by approximately one third of members of an FDA panel and also by approximately one third of an MOC Exam Review Course 2008 faculty. A similar percentage, at least 5 of 18 of the new AOS members attending this year's meeting, reported financial conflicts in the 2007 AAO Program book. Perhaps the physician industry alliance is then merely a sign of present times.

The recent 2008 report of the AAMC task force on industry funding of medical education realistically observes case that "over recent decades, medical schools and teaching hospitals have become increasingly dependent on industry support of their core educational missions." As such, rather than banning industry participation in CME, they propose that the AAMC collaborate with ACCME to create audit mechanisms to spot-review or audit programs for consistency.⁵

Financial conflicts impact on the credibility of ophthalmology as a whole. At the recent FDA panel meeting last month on LASIK, disgruntled patients implored the FDA to exclude certain organizations and individuals from participating in development of a proposed prospective LASIK satisfaction survey. These patients argued that the named organizations and physicians had industry ties that biased them and would negate the results of any study in which they were a participant.

Indeed, it would be hard to argue against the proposal that CME has been used to influence the practice of medicine by endorsing drugs or devices. Can we roll the clock back and eliminate the foothold of industry in CME? I do not think so. There is; however, still merit in the cautionary note of the danger of financial conflicts influencing medical decision making. Although many in the medical profession may assume that there is no danger of infringement of industry upon our herd, I believe it is important to be careful of those who are among us.

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DR. PAUL R. LICHTER.: Thank you, Dr. Weiss, for your thoughtful discussion and for bringing up some very critical points. Industry certainly has the money for CME and uses it to bribe us and hold us hostage. However, while many departments and organizations think that they need this money to survive, it may well be that they can get along without it. When departments and organizations look at their finances without the tainted money, they would figure out another way to get their jobs done—including their CME programs. For example, my own department has never taken money for continuing medical education. We do not take food, we do not accept money for speakers, and we manage to get along just fine without it. We do not have a major endowment such that money is no object. Could we use the tainted money? Sure we could, but the price we would pay is not worth it, in our view. The ethical issue really comes to the physicians' duty toward their patients. As physicians we are bound by the Hippocratic Oath to serve our patients above our own needs. The literature shows unequivocally that when physicians take gifts from industry, it is to the detriment of patients and the public. This is a difficult topic, and surely it will go on being discussed. However, when we say there are two sides to the issue it reminds me of the tobacco industry years ago saying, "we need more research". If you can continue having CME funding by industry debated as a two-sided issue, then that is where the pharmaceutical and device industries want it. That way, there will be continued discussion, but no action.