

Examining the Value of Commercially Supported CME

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Commercial support of continuing medical education/continuing professional development (CME/CPD) is a fact of life currently, though under attack from several sources. Does it have a positive or negative value to industry, to physicians, to society, and to CME professionals? There is sufficient evidence to support positive value to industry. There is insufficient evidence to support positive or negative value to physicians or society. There is reason to continue commercial support while broadening the base of support beyond the pharmaceutical industry, not only to avoid perception of bias but also to address CME/CPD needs that do not fit in therapeutic categories. CME professionalism does not depend on commercial support.

Key Words: education, medical, continuing, industry support, continuing professional development

Does commercial support of continuing medical education (CME) or continuing professional development (CPD) contribute value to its supporters—the pharmaceutical and medical device industries? Does commercial support enhance or detract from the value of CME/CPD to the medical profession and to society, and how does it affect those CME professionals involved in its planning and evaluation? These questions, posed to me by the editor of this journal, have been examined with much emotion and little hard data in the past 2 years. This article will seek to provide a rational basis for answers, based on personal interactions with many medical education managers in the pharmaceutical industry.

Prior to answering the questions regarding value to industry, we first examine whether CME has been proven effective—regardless of where the financing comes from. Mansouri and Lockyer¹ and Marinopoulos et al² both conducted meta-analyses and came to similar conclusions: that though the quality of evidence was low, and that CME appears to be effective to some degree in knowledge gain, physician performance, and patient outcome, there is no clear documented relationship between effectiveness and source of support.

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Assessing the Value of CME/CPD to Commercial Supporters

Does support of accredited CME/CPD provide value to industry? Judging by the investment industry has made, exceeding \$1 billion in 2007, the answer appears to be yes. Pharmaceutical and device companies provide products to diagnose or cure disease and to improve the health of patients. These products don't exist in a vacuum; they require an environment of education for health care providers and their patients. Companies rely on medical education—both accredited and nonaccredited—as one means of assuring that physicians are fully informed about the appropriate use of their products, and the diagnoses to which they apply.

So long as the educational content remains consistent with labeling approved by the Food and Drug Administration, industry may contract for nonaccredited or promotional education, which is not subject to the rules of the Accreditation Council for Continuing Medical Education (ACCME). Accredited CME requires the provider to maintain standards of quality and independence designed to eliminate bias and to provide fair balance. Accredited CME is necessary for discussions that go beyond FDA-approved labeling, and is also considered by industry to be of higher value to physicians.

Here are some specific purposes of CME/CPD that benefit industry:

1. Research findings that may benefit patient care can be shared with practitioners before products are introduced. Research may demonstrate new methods of diagnosis based on changed understanding of the disease, or new mechanisms of therapeutic action. As Barbara Barnes stated when she was president of the Society for Academic CME: "It is critically important to inform physicians about new research findings.

In many cases, the most up-to-date information is held by commercial entities." 3 Unfortunately, the ACCME seeks to discourage any contact between an accredited provider and a commercial supporter, even though the latter might have a valuable contribution to make, and a principal investigator may be ruled ineligible to participate in a CME activity because of presumed conflict of interest.

2. Physicians can gain better knowledge of the diagnostic and therapeutic alternatives available in managing patient care (in areas of therapeutic interest to supporters). The Pharmaceutical Research and Manufacturers Association (PhRMA) in its new Code of Interactions with Healthcare Professionals states that "CME helps physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. Such . . . support . . . is intended to support education on a full range of treatment options and not to promote a particular medicine." 4 Correctly presented, a commercially supported program will also indicate when a particular product or dosage form is not clearly indicated.

The benefit to the supporter is clearly outlined by Mike Saxton, senior professional education director of Pfizer: "We don't give grants that have no relation to our interests . . . We are looking for gaps in healthcare performance in which the patients' interests align with the healthcare providers' interest, which also align with our own."5

3. Physicians can learn about a range of off-label uses of a drug that may benefit some patients. CME/CPD, if developed appropriately, is a safe-harbor way to share peer-reviewed research studies of off-label uses with practitioners. This is particularly important in specialties such as oncology, psychiatry, and pediatrics, where there is rapid experimentation with an approved drug and where there can be a substantial time lag between research reports and submission of label change to the FDA—if the latter ever occurs. This is clearly an area where abuse has occurred, and therefore such activities need to be carefully controlled under ACCME regulations for fair balance and resolution of conflicts of interest.

The Value of Commercially Supported CME/CPD to Physicians and Society

Does commercial support enhance or detract from the value of accredited CME/CPD to the medical profession and to society? Cervero and He, in a study commissioned by the Accreditation Council for CME (ACCME), could find no evidence that commercial support did—or did not—influence doctors inappropriately, nor could they find any evidentiary link between commercial support of CME and patient care outcomes.6

The answer to the question, therefore, is that we do not know. Critics of commercial support, such as participants in the recent Macy Foundation conference, rely on limited personal observation to support their argument that industry support "distorts continuing education . . . Bias, either by appearance or reality, has become woven into the very fabric of continuing education." We need studies comparing the effectiveness of CME activities supported by industry versus the same activities supported by the profession before the question can be correctly answered. The North American Association of Medical Education and Communications Companies (NAAMECC) has been attempting to organize and fund such a study. In the meantime, the following observations can be made, based on comments from industry leaders, and not documented in peer-reviewed literature:

- 1. Commercial support enables availability of more high-quality CME/CPD than would otherwise be possible. Industry currently funds more than 50% of all accredited CME. Even if that balance changes, rapid withdrawal of all industry support might be damaging to physician competence and patient health in areas related to industry products. Hilary Schmidt, associate vice president for medical education and communications at Sanofi-aventis, explains: "Industry has as part of its mission to educate on the safe, effective and appropriate use of therapies. Supporting 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."5
- 2. The ACCME Standards for Commercial Support, when followed completely, provide safeguards against bias that may affect physician judgment. Companies are not allowed to control content nor choice of speaker. In a recent talk to the Coalition for Healthcare Communication, Cathryn Clary, vice president of Pfizer for US external medical affairs, said: "Pfizer should promote change strategies [in CME/CPD] that are controlled by the health professions, are based on sound assessment of needs and outcomes and . . . integrate education with quality improvement strategies."8
- 3. Accredited providers need to broaden their base of support to reduce the risk of commercial bias and the temptation to provide activities only in certain therapeutic areas. It is all too easy for an accredited provider to maintain a support relationship with only 1-3 companies, and therefore limit the range of topics addressed and the choice of speakers to those fitting the therapeutic categories of their supporters. This is a disservice to physicians and to their patients. Accredited providers benefit professionals and society by covering a wide range of documented health care needs and seeking grants from multiple supporters, including not only pharmaceutical and device companies, but also payers (health insurers, large employers, and government), foundations, and physicians themselves.
- 4. The CME/CPD field needs to do a better job of informing patients, the media, politicians, and the general public of the value of its programming, whether commercially supported or not. This is not a job for industry; surveys indicate that most Americans believe that industry gifts, including support of CME/CPD, affect physicians' prescribing habits. Once again, independent studies are needed to support the value—or harm-to society from commercial support of accredited CME/CPD. Wyeth Laboratories recently conducted a study "which demonstrated that at least 7 million patients [potentially] received improved patient care as a result of CME activities the company funded," according to a report in Medical Meetings magazine. 9 No further data on this study were available, and its funding source raises questions regarding validity. Medical schools and societies need to do

JOURNAL OF CONTINUING EDUCATION IN THE HEALTH PROFESSIONS-29(1), 2009 DOI: 10.1002/chp well-documented research on their own activities, and share the results with the public at large.

The Value of Commercially Supported CME/CPD to CME/CPD Leadership

Does commercial support of CME/CPD enhance or detract from the career value of those involved in planning, evaluation, and policy making associated with CME/CPD? This is another question that cannot be answered with the evidence available. Career advancement of a CME professional does not appear to be dependent on the extent to which his/her activities were supported by industry. Here are some further observations:

- Some CME professionals have enhanced their careers by accepting positions with commercial supporters or vice versa. To name a few, Jennifer Spear Smith of Wyeth learned the field at a medical education company. Robert Kristofco of Pfizer moved from the University of Alabama. Jacqueline Mayhew of Pfizer moved from the American Heart Association. Robert Orsetti moved from industry to the University of Medicine and Dentistry of New Jersey. Keith McGregor moved from Sanofi to the European Society of Cardiology.
- 2. Professionalism in CME/CPD is not dependent on funding source but on capability. For a professional to advance his/her career, it is necessary to be an effective manager of resources, and to understand the basic principles of needs assessment, program planning, outcomes measurement, and management of risk. That is why the new National Commission for Certification of CME Professionals (NC-CME) has a role to play in creating a standard platform for assessing competence.¹⁰ NC-CME at this time depends primarily on examination fees paid by individuals or their employers, and on charitable gifts from a variety of donors.

Summary and Conclusions

CME/CPD does demonstrate value to its commercial supporters by providing benefits in physician knowledge, skills, and competence, which may enhance not only the supporters' image but also the correct prescribing of its products. We lack sufficient evidence regarding the influence commercial support has on physician behavior or patient outcomes; good studies are called for. We do not know that commercial support affects career advancement for CME professionals positively or negatively, but it is not likely to be the determining factor.

More research is required on the impact of commercial support, as is a change in direction of support of CME/CPD to a broader base—multiple sponsors not only from the pharmaceutical industry but also from other sources. That will

Lessons for Practice

- Industry values fair, balanced education both for its own benefit and that of physicians and patients.
- There is no clear evidence to prove or disprove bias resulting from commercial support, without which there might be a reduction in quality CME/CPD.
- The careers of CME professionals are not linked to commercial support, but may benefit from certification.

enable a broader base of physician/patient needs for practice improvement to be addressed.

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