A View from Industry: The Foundations of Future Commercial Support and a Call for Action

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Based on a model of industry support that aligns with the emerging performance-improvement approach to continuing medical education (CME), a call to action is made for the transformation of commercial support. Today, commercial support, like the CME profession, is linked largely to educational activities of far less value to patients than the model now emerging to address professional practice gaps. The new model could help ameliorate lingering concerns about the presence of commercial support, but it also will require fundamental changes in perspective and procedures by both industry and CME providers.

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

Foundation for Commercial Support

The core competencies of the Maintenance of Certification (MoC) program in the United States also form the foundation for commercial support of continuing medical education (CME) and continuing professional development (CPD). The competencies emphasize patient-centered care, medical knowledge, communication, professionalism, systems-based practice, and practice-based learning and improvement; they reflect the boundaries of a system within which commercial support should be provided. In FIGURE 1, the overlap of three circles representing patient needs, health care system quality gaps, and health care provider performance gaps, creates the boundaries of MoC-based medical education needs. These boundaries also may include a fourth circle where commercial supporters’ business needs can be placed. The optimal area of commercial support can then be defined as the convergence of mutual interests where there is an overlap between MoC-based medical education needs and business interests of the biomedical research industry. To receive commercial support, the learning intervention must: (1) represent a viable benefit to patients, (2) be based on needs identified by a health care system quality gap and/or a health care provider performance gap, and (3) be compatible with the business of the industry. This model also suggests why it is in industry’s interest to support any of the 6 competency areas rather than having a limited view of its role as focused only on competency area number 2, medical knowledge. For example, if provider communication skills are among the root causes of a particular performance gap, industry should recognize support of this competency as within the boundaries of mutual interest. If commercial support of CPD is constructed on the foundation of this MoC-based triad of needs, then the likelihood of bias and the risk for CME-provider independence could largely be mitigated, if not almost entirely eliminated. Multiple checks and balances establish evidence-based needs and reduce the risk of inappropriate commercial influences. This is a system of support that is learner centric, performance driven, evidence based, and reflects the quality-improvement needs of a care-delivery system.

Implications for the Role of Commercial Support

Ultimately, the medical profession must determine what the role of commercial support will be in CME. Then, industry must comply—as rapidly as possible—with whatever option is chosen. In the meantime, industry does not fulfill its responsibility to patients by waiting passively for an extended debate to be resolved. Rather, industry should implement policy changes that can move its practices closer to the principles currently being articulated by the profession. TABLE 1 presents 3 options from an industry perspective: (1) continue the current approach to industry support of CME, (2) eliminate industry funding, or (3) transform the future of commercial support.

The status quo is unacceptable. Strong sentiment is voiced by some that the financial resources provided to support...
traditional CME rarely result in meaningful improvements in patient care. There is, in fact, wide public and professional criticism concerning the commercial influence exerted by industry educational grants.4,5 There are some in industry who associate traditional CME support with high compliance risk—any real or perceived actions leading to the potential for undue influence or bias to be introduced into independent CME in an intentional manner or in a manner whose connections with conflict of interest issues could be perceived as influenced by commercial interests. There simply is very little mutual value in the present model: It has low educational effectiveness and higher compliance risks than the model proposed in FIGURE 1. It is for these two reasons that companies who see support of only traditional CME as their role will increasingly reduce funding and in some cases stop supporting CME within the next 5 years, unless a new model of commercial support is adopted. Industry will in effect endorse the option brought to light by the Macy Foundation2 for the elimination of commercial support within the current 5-year time frame. If the medical profession ultimately were to mandate the total elimination of commercial support, industry should support the call for a 5-year phase-out period versus an immediate cutoff. A sudden cessation of funding could compromise the ability of CME providers to plan and conduct worthwhile educational activities; create widespread financial disruptions; and negatively affect patient safety.

The Medical Education Group at Pfizer favors the transformation model for commercial support, an evidenced-based approach defined by the boundaries identified in FIGURE 1. It optimally aligns the value of CME support for patients, the medical profession, and industry.

### Implications for the Value of CME to Commercial Supporters

What is the value of CME to commercial supporters? The question is often posed; the answer can be no different from the sum of the whole value to patients, to the medical profession, and to industry. If the central purposes of industry are to improve health for people around the world and to

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**TABLE 1. Industry CPD Support Options for 2008–2013**

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<th>Future Support Option</th>
<th>Pro</th>
<th>Con</th>
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<tr>
<td><strong>Status Quo</strong> Continue current approach</td>
<td>1. Less disruptive to CME providers 2. More familiar to industry</td>
<td>1. Low educational effectiveness 2. ACCME standards of accreditation currently not rigorous enough on organizational conflict of interest 3. Change is too slow for environment 4. Industry criticism remains 5. Company compliance risk is highest</td>
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<tr>
<td><strong>Eliminate</strong> Stop industry funding completely</td>
<td>1. Reduces perceptions of bias 2. Helps alleviate budget pressures on industry</td>
<td>1. No ability to support credible independent education that accelerates evidence-based innovation adoption 2. Removes a resource to help close health care quality gaps 3. Current CME system dependency 4. Does not manage the majority of real conflict of interest in CME</td>
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create value for stakeholders, then the value ascribed for industry has to transcend self-interest only and add value to patients and the medical profession. All 3 stakeholders must realize the value of industry support if that support is to be effectively utilized. If industry is the primary recipient of value, then support is likely predicated on a quid pro quo that compromises the independence of the CME provider.

Commercially supported activities focused on “therapeutics” or “therapeutic areas” are becoming cultural artifacts of an era when decisions were made by commercial parts of companies. The words remain as constant reminders of the potential for bias, and they should always raise caution in the minds of CME providers or industry personnel who communicate with one another. The narrow knowledge-only approach to traditional CME actually limits the potential for contributing to patient safety and improving total care management. Effectively using the right treatment plan at the right time for the right patient requires successful execution of all the core competencies described earlier: patient care, medical knowledge, practice-based learning and improvement, interpersonal and communications skills, professionalism, and systems-based practice. Industry support is too often narrowly focused, both by commercial supporters and provider expectations around the competency of medical knowledge related to new therapeutics. The status quo of industry support has fostered the continuation of a “meetings-based” CME economy. This history of support suggests it may actually stifle innovation and perpetuate inefficient and ineffective use of learning resources of all kinds. Utilizing the convergence of interests model in Figure 1, this can be seen as a narrow focus, outside of the center of mutual value; the literature is clear, it is unlikely to lead to improved performance. Additionally, the risk for bias or loss of independence is significantly increased when education support is focused simply on a gap in knowledge outside of the context of practice or systems of care. We have described elsewhere a taxonomy of communication levels for industry attached to the view that there is less potential for bias the more closely aligned communications are with the center of this model. Communications range from discussions around performance or quality gaps based on publicly available measures at the center through 5 other levels that move increasingly farther away from the ideal.

The value, therefore, to the medical profession, commercial supporters, and most importantly patients, is increased when the focus is on performance-improvement CME that embraces the full set of 6 core competencies of the American Board of Medical Specialties and the Accreditation Council for Graduate Medical Education.

Implications on Funding Mechanisms

The professional issues raised by today’s overdependence on industry and lack of balanced funding are not new. The risks of this imbalance for quality of care ultimately are the responsibility of the medical profession, and it is inappropriate to blame or credit the support of industry for the quality of CME or for the whole of patient care. Instead, the heart of the problem may be lack of funding from other sources. What industry should do is recognize its role in the evolution of this problem and support the medical profession’s move toward balanced funding by adopting policies and procedures that encourage less dependency on industry. If we are to adopt the model of commercial support described herein, where the overlapping zones of mutual value are clear, then it should be expected that provider organizations support their own initiatives in meaningful ways. The litmus test, therefore, for how aligned a proposal is with the mission of the CME-provider organization is the degree to which the provider organization contributes its own resources to the activity. For example, in contrast to today’s reality, it is our view that support from any one commercial entity should not exceed 50% for a major activity. Furthermore, any organization requiring too high a percentage of commercial support to maintain its overall program should be required to disclose the percentage (perhaps more than 50%) and perhaps be sanctioned in other ways.

Industry veterans can share many experiences demonstrating that a strong “entitlement” mentality still exists among providers. There is an expectation that industry will continue funding the activities it has in the past, including low-impact CME and noneducational expenses like meals. It remains common for industry personnel to have to defend externally why they declined grants where the major costs were for food in an educational setting not conducive to practice-based learning and improvement. This culture of entitlement, that we acknowledge continues to exist among commercial supporters as well, needs to change. Change will occur naturally and more easily if proposals are mission-aligned around patient-centric values rather than driven primarily by a business-development revenue model. In parallel with this view, commercial support should increasingly be understood as inappropriate for supporting noneducational expenses like meals that are not directly beneficial to learning. This reflects the spirit of concerns expressed by the profession of an overdependence on industry funding, and it is directionally the same as industry guidelines prohibiting payment for meals in most settings. Today, there is no established standard upon which to develop informed policies for balanced funding requirements.

In addition to working together towards balanced funding, new approaches to awarding grants can be pursued that further mitigate risks of bias while simultaneously aligning the value derived by all stakeholders in the system. Interim approaches like performance-improvement CME or block grants to regional, state, or health care system organizations may lead to mechanisms similar to institutional review boards (IRB) with the awards of individual grants decided by representatives of the CME profession external to industry. The cornerstone of any new successful grant-awarding mechanisms will be the recognition that industry, like patients,
health care providers, and health care delivery systems, shares in the value of its financial support as illustrated in FIGURE 1. Otherwise, these efforts simply may lead industry to eliminate its support of CPD in the future.

Call for Action

In order to move as rapidly as possible to implement the performance-improvement model of commercial support, consideration needs to be given to the following changes:

- Industry should fund only the highest quality change strategies; typically
  - controlled by the health professions
  - based on needs defined by health care provider performance gaps or health care system quality gaps
  - incorporating clearly articulated interactive methods that facilitate self assessment and reflection
  - providing physicians with opportunities to gain feedback on their performance
  - integrating education with quality-improvement strategies
  - designed to change competency, performance, and/or patient outcomes

- Industry should support and contribute to the research and intellectual framework of effective CPD.

- Commercial support should be provided only to those organizations that are engaged in patient care or represent those who deliver patient care. These organizations are the only ones in a position to align patients and medical professionals in the context of a health care system in order to achieve the highest recognized standards of quality.

- Industry should continue to support proposals that include services from other stakeholder groups, including medical education and communications companies and nonprofit foundations, when the proposals are valued by the medical profession and the services provide essential support. For example, funding should still be available to an academic medical center that chooses to employ the services of a medical education and communication company as an education partner.

- No funding should be provided directly or indirectly to any organizations in a position to influence content that do not eliminate financial conflicts of interests where compensation systems overshadow patient-safety concerns.a

- CME providers should accept funding only from commercial supporters who are transparent about grants awarded, and industry should support only providers willing to be fully transparent about all elements of their proposals.

- End industry funding within the 5-year 2013 timeframe called for by the Macy report2 for all noneducational expenses that do not directly benefit learning.

- Industry should support only grant proposals that have additional financial support from other sources.

- Standards need to be articulated by the medical profession describing what level of funding constitutes an overdependence on commercial support from which industry can derive policy standards for both organizational and individual grant eligibility.

- Explore new mechanisms to award grants that build on interim approaches like block grants. Examples include the emergence of future IRB-type mechanisms with the provision of individual grant decisions handled by the medical profession while industry support remains focused only on those areas where its interests overlap the medical profession’s.

- Recognize that any charitable contribution model of industry support will lead to the elimination of funding by industry. These models do not recognize the mutual value of educational support necessary to sustain industry funding and are viewed as increasing litigation risk to industry based on recognizing these undesignated contributions as “gifts” to customers that can invoke anti-kickback statutes.

- Commercial supporters should not fund activities that include faculty employed by that company as promotional speakers on topics similar to the activity. CME providers should seek support for such activities from commercial supporters who do not employ the faculty through promotional speaking.

- Providers who set up any promotional opportunities as agents for industry other than traditional exhibit opportunities should be excluded from receiving direct or indirect industry support of independent medical education.

- Allow only interaction between industry and CME professionals who have demonstrated competence as defined by the CME profession.

- Industry must change its perspective from transactional support of meetings and events through grant administration to one recognizing its support role in facilitating learning and change to improve patient care within the context of health care systems while simultaneously developing the requisite competencies to make this change.

Conclusions

Continuing medical education is recognized increasingly as a strategic component accelerating health care performance improvement efforts within many organizations. In today’s environment of change and increasingly constrained resources, the question to be debated is not how to separate or eliminate commercial support for CME, but more fundamentally how to change the way it is used. Neither the status quo nor the complete elimination of industry support is in the best interest of patients. In the boundaries defined by a convergence of interests model, it is in the public interest to draw on commercial support as one resource to improve performance around professional practice gaps. The model holds great promise to more effectively manage current conflict of interest and potential bias issues. To maximally benefit patients, both industry and CME providers need to change perspectives, revise policies, and realign processes

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aIf any part of a compensation system is based on a percentage of grant funds raised or expected to be raised, this is out of compliance with existing ethical fundraising standards represented by Standard 16 of the Association of Fundraising Professionals’ Code of Ethical Principles and Standards of Professional Practice.13 This type of conflict of interest has been the norm for some provider types and remains an issue not being addressed or understood.
Lessons for Practice

- As rapidly as possible, commercial support should be realigned with practice-based learning and improvement founded on a performance-improvement model of continuing professional development.
- Risks of commercial bias are mitigated largely by the checks and balances of defining the boundaries of commercial support as the overlapping interests of patients and providers, within the context of health care systems.
- Industry should recognize the mutual value of improving the overall effectiveness of continuing professional development by supporting and contributing to the research and intellectual framework of the field.
- Transparency should be required for commercial supporters and providers.
- Providers who utilize compensation systems that do not conform to ethical fundraising standards should be excluded from receiving commercial support.
- Balanced funding can be encouraged by eliminating commercial support of noneducational expenses.
- Professional competency as defined by the CME profession should be required of all personnel involved with interactions between provider and commercial support personnel.

to harmonize with this transformational view of industry support.

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References