

CME, COIs, and the Spectre of Big Pharma: Is the Science of Medicine for Sale?

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CME

On the patient end of medical care and treatment, there is often the assumption that the decision-making process behind that care is based on the factual and applicable principles of the clinical degree training process. Within the biomedical community, however, the absolute necessity of assimilating current findings and up-to-date practices into the care that reaches patients is indisputable. Continuing medical education (CME) is not only a logical step in the ever-more-embraced transition to evidence-based medicine, it is an enforced practice required for medical licensure in the US on a state by state basis.

This process is overseen by state medical licensure boards, which usually require practitioners to complete on a biannual basis a minimum number of continuing education credits, attained from providers certified by the Accreditation Council for Continuing Medical Education (ACCME).^{1,2} Certified providers of CME range from academic centers and medical journals to the more recent, so-called medical education communication companies (MECCs). A combination of these might as well be incorporated into CME activities sponsored by physician societies like the American Medical Association (AMA). CME credits are thus obtained through the completion of coursework, participation in sponsored events/lectures, and assessment of medical literature read (most CME-accredited journals include short tests dealing with recent articles).

COIs

With the expansive successes of pharmaceutical companies and medical device manufacturers in recent decades, their realm of influence has grown into nearly all facets of the health service sector. Outside the contribution of many essential medical developments, the influx of for-profit commercial players has consequently generated the myriad of conflicts of interest (COIs) which now plague the landscape of medical practice and related research and academia. It is widely accepted that a central dilemma of the pharmaceutical industry is whether to “develop new drugs or promote existing ones”³, but it remains to be questioned what its role is in the development and dissemination of useful, valid medical science.

That these sizeable commercial entities expect to maintain their revenues to support any of the aforementioned is understandable. However, when looking at the vast amounts of revenues that are invested in production and distribution, research and development, and promotion, it is understandable that the overwhelming sums

invested in promotion, in particular, are the subject of controversy. Enough to raise the eyebrows of bioethicists alone, the \$57.5 billion total spent on promotion in the US in 2004, according to one estimate, was almost twice the generally accepted amount spent on R&D.⁴

COIs arise at the intersection of industry efforts with the efforts of health professionals and medical educators due to certain obligations which, at times to the detriment of patient care, have proven in many cases to be mutually exclusive. Within the scope of CME, academic centers/research institutions as well as publishers of medical literature are obligated to provide doctors with the information that best enables them to treat their patients. MECCs and pharmaceutical companies, on the other hand, are vulnerable to circumstances in which they are inclined towards serving their own corporate fiscal interests and have in numerous cases confused these interests with those of CME consumers and the patients affected by this information. Commercial support for CME in excess of \$1 billion in 2008, as reported by the ACCME⁵, represents just a fraction of the industry funds used in reaching out to physicians.

MECCs AND CME

The problem of COIs is further illustrated by the level of industry funding of MECCs involved in CME activities. ACCME-certified MECCs, which are independent for-profit companies in many cases established by advertising or marketing agencies, plan and organize CME events where doctors are often paid as speakers.⁶ Since it is understood that MECCs depend on pharmaceutical company support for more than 80% of their revenues⁷, it is difficult to understand how these organizations are able to provide unbiased CME content. Is it unreasonable to expect these companies to utilize physicians with whom they –the MECCs and/or their sponsors– are familiar, and therefore have congruous vested interests?

COIs IN ACADEMIC CME SETTINGS

Academic institutions, such as universities and medical schools, are a central front in providing both the research that fuels medical developments for and the conferring of medical knowledge to future and current medical professionals. Medical researchers and lecturers are not only subject to academic commitments under the mission/policies of their own institutions, but may take

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on other pledges in the solicitation of additional support of their teaching or research efforts from external public or private sources. These are in many cases the people responsible for organizing courses and events for which CME credits are awarded. The 2008 Harrison Survey of North American Medical Colleges by the American Association of Medical Colleges and the Society for Academic Continuing Medical Education found that 56% of revenues used for academic CME at reporting US schools came from commercial sources.⁸ It is naturally confusing and difficult for each of these entities to separate their obligations and responsibilities, since the majority of the funding is provided by companies with vested interests in promoting their own products.

A much publicized example is the case of psychiatrist Charles Nemeroff, who was forced to step down as Chair of the Department of Psychiatry and Behavioral Sciences at Emory University School of Medicine, and became the subject of national investigation. Interest focused on COIs brought to light stemmed from his failure to disclose financial relationships and ties to industry, at one point having consulted for as many as 21 drug and device companies simultaneously.^{9,10} As surprising was Emory's position subsequent to their internal COI investigation; after uncovering unreported income in violation of university policies amounting to over \$800,000 from just one company willing to cooperate with the investigation, GlaxoSmithKline, he "...[was] limited to accepting payment for ACCME-accredited speaking engagements sponsored by academic institutions or professional societies."¹¹ One wonders what occurs within comparable academic CME settings. This was further exacerbated by the fact that he acted in violation of conditions governing his receiving of taxpayer-supported NIH funds for his research activities.¹² As a result, Nemeroff, though a renowned physician in his own right, has also become a figure symbolic for the wider systemic problem of COIs among academics involved in medical education and research.

COIs IN CME LITERATURE

The area at the epicenter of academic bioethical contention is also at the heart of medical knowledge—documentation in the form of biomedical literature, which has more and more been the target of industry promotion efforts. It is this packaging and presentation which is the substance of continuing education materials represented by current research and review. COIs stem from two major problematic practices in medical literature content and authorship: misrepresentation of authorship/findings and support for research by profit-oriented commercial parties. Nowhere is this more apparent than in the controversial practice of industry-supported "ghost" authorship, whereby the messages attributed to reputable authors are generated or influenced by subcontracted private parties not cited as contributors. In perhaps the most convoluted manifestation

of ghostwriting, drug companies fund studies through contract research organizations.¹³ In some of these cases, MECCs paid by pharmaceutical companies will then prepare or shape manuscripts for publication in medical journals and pay doctors to submit the work under their names.^{13,14} It is not altogether uncommon that input in such cases comes from "honorary" authors who are not the principle researchers.¹⁵ Nonetheless, major journals that serve as sources of CME content continue to fall prey to ghostwriting "campaigns," forcing journals to come together to change editorial practices, as in the case of the International Committee of Medical Journal Editors (ICMJE).¹⁶ In findings presented to the September 2009 International Congress on Peer Review and Biomedical Publication, editors of the *Journal of the American Medical Association (JAMA)* gauged the prevalence of ghostwritten articles in six of the major medical research journals, ranging from 14% at the *New England Journal of Medicine (NEJM)*, ironically the focus of current furor, to an astounding 39% in *Nature Medicine*.¹⁷

CONCLUSIONS

Patients and medical professionals deserve to know the unbiased findings of legitimate medical research in the generation of a consensus regarding medical practices. So too should the scientific record be maintained. These basic tenants are reflected in the public outrage over industry manipulation of medical education. Public outcry in the US is forcing hands to promote oversight, such as the extensive investigative work by Senator Grassley (IA-R)^{9-12,18,19}, revealing the prevalence of corrupted medical academia and the lack of basic disclosure policies at institutions like the NIH, which even last year did not require disclosure of COIs from grantees.²⁰ This and related scrutiny has had an effect, driving pharmaceutical companies from supporting MECCs and directing more of their CME-sponsorship funds to physician societies.^{5,21,22} Academic institutions have heeded the public outrage and pressure of investigations, exposing biases in medical education activities for which they are responsible and branding misrepresentation of research as "on a continuum with plagiarism," in the words of University of Pennsylvania Center for Bioethics Director Arthur Kaplan.¹⁹

When it comes to sources of CME literature, the responses of academic journals to the overwhelming presence of COIs have included the stringent new *JAMA* policies that likely led to their drop in "commercially funded papers...from 60% to 47%."¹⁶ This might reflect increased rejection of such articles and, potentially, that industry-influenced players are avoiding submission. Editors worldwide are taking a stand and taking a microscope to their submissions, from outspoken *British Medical Journal (BMJ)* editors castigating drug company-biased articles²³ to the *Chinese Medical Journal* investigating ghostwriting²⁴, culminating in the in October 2009 arrival on a policy for the uniform disclosure

of COIs in paper submissions to ICMJE journals.²⁵ From Merck to GlaxoSmithKline to Wyeth (now part of Pfizer), drug companies have also instituted reforms seeking to improve upon disclosure practices. Still, abuses continue, according to editors of major publications, who claim to still receive large numbers of suspicious papers that “offer favorable reviews for new drugs apparently penned by authors who had not previously published on that topic” or others seeming “to market off-label uses of drugs.”¹⁶

The evolution of these standards is essential to ensuring patients receive the objectively-researched treatments and care that non-biased CME should offer doctors. This is not compatible with the bias that affects the CME process at every level- be it at the basic science level, where only certain projects are funded and certain outcomes reported, or in lecture form, where educators allow the novelty marketing of products to influence their presentations. The bioethical implications are immense when COIs are left unchecked and individuals are driven by obligations that would lead them to transgress against the best interests of patients. If doctors are bound by the Hippocratic Oath, under what code need researchers, producers of medical supplies, educators, and publishers of biomedical literature swear?

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