Editorial

Industry-Sponsored Medical Education — In the Quest for Professional Integrity and Legal Certainty

Abstract
Industry-sponsored medical education is a much disputed issue. So far, there has been no regulatory framework which provides clear and definite rules as to whether and under what circumstances the sponsorship of medical education is acceptable. State regulation does not exist, or confines itself to a very general principle. Professional regulation, even though applied frequently, is rather vague and indefinite, raising the general question as to whether self-regulation is the right approach at all. Certainly, self-regulation by industry cannot and should not replace other regulatory approaches. Ultimately, advertising law in general and the European Directive 2001/83/EC specifically, might be a good starting point in providing legal certainty and ensuring the independence of medical education. Swiss advertising law illustrates how the principles of the European Directive could be implemented clearly and unambiguously.

Keywords
professional regulation; medical education; sponsorship; advertising; self-regulation

The Controversy Relating to Industry-Sponsored Medical Education

The cooperation between industry and the medical profession can assume various forms and quite often, the distinction between professional cooperation and marketing becomes blurred. The latter is especially true for matters involving the sponsorship of continuing medical education.[1] In many countries, continuing medical education depends heavily on financial support received from pharmaceutical companies. It is a widely acknowledged fact that nowadays, without the sponsorship provided by industry, the variety and multiplicity of medical education would no longer be possible. However, the sponsorship of medical education is not without controversy, either in Europe or in the US. Only recently have physicians in the US initiated discussions relating to prohibition of every form of financial contributions by pharmaceutical companies in order to avoid the risk of conflicts of interest in the medical sector[2] — their aim being to ban any form

1) Instead of continuing medical education (CME) one may also use the term continuing professional development (CPD).

2) Brennan/Rothman/Blank/Blumenthal/Chimonas/Cohen/Goldman/Kassirer/Kimball/Naughton/Smelser, Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers, JAMA 295 (2006), 429.

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of direct or indirect sponsorship of medical education. Deposits into central medical funding-pools which would then distribute the funds among the various individual education programs is intended as the only admissible means of financial support.[3] In Europe also, there is an ongoing discussion about the independence of medical education and about doctors' professional integrity in general. The issue is not only discussed in medical journals and magazines but has also prompted physicians to launch various initiatives which discourage any form of financial support by industry.[4]

The possibilities of conflicts of interests arising as a consequence of the sponsorship of medical education should not come as a surprise. Companies that invest a considerable portion of their profits in the funding of medical congresses, training programs, and the like legitimately pursue their own economic interests at the same time. It would be unrealistic to assume that such sponsors would not expect any consideration for their money. The discussion therefore does not relate to whether or not sponsorship of medical education should be regulated, but concerns the appropriate choice of regulatory body and the necessary limitations to be imposed. Basically regulation is conceivable on four different levels: state regulation, physicians' professional regulation, industry self-regulation, or advertising law. However, none of the above approaches has so far provided a clear and consistent means of regulating the sponsorship of medical education. Rather, regulatory efforts have confined themselves to being rather vague and general, thus leaving wide room for subjective interpretation throughout Europe. Clear and unambiguous guidelines both aimed at providing legal certainty to physicians and industry and ensuring the independence and integrity of the medical profession are required.

State Regulation

So far, states have been reluctant to regulate the sponsorship of medical education. One of the few examples of regulation which refers to the issue of funding of medical education can be found under sec. 95d SGB V (Book V of the German Social Code). According to sec. 95d SGB V, continuing medical education is mandatory for SHI-accredited physicians. Furthermore, sec. 95d SGB V also addresses the content and concept of medical education. According to the provision, the content of medical education has to be in accordance with the current state of scientific knowledge and has to be "independent of economic interests". This latter requirement also refers to the issue of sponsorship of medical educa-

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3) Id. at 431-432.

4) For the UK see e.g. NoFreeLunch-UK.org (www.nofreelunch-uk.org), for Germany MEZIS ("Mein Essen Zahl Ich Selbst"; www.mezis.de).

tion. Yet a common understanding of the phrase "independent of economic interests" has so far not been attained amongst actors within the health sector. Some argue that medical education is independent of economic interests only where it is entirely independent of any form of industrial funding. On the other hand, it is also argued that sec. 95d SGB V refers only to those forms of medical education which are merely marketing events without any educational or scientific demand.

The practical relevance of sec. 95d SGB V is thus limited. After all, sec. 95d SGB V also leaves it to the medical associations to decide on the admissibility of sponsored medical education. The same is true for other European states. Although a number of states such as Austria and Switzerland have ruled continuing medical education to be mandatory, most of such states have not set any legal requirements as to the organization or funding of medical education.[5] Instead, they have left these decisions to their national medical associations. This general reluctance may first of all be due to the belief that medical education related issues constitute a genuine matter in which the medical profession alone should be involved and therefore every kind of paternalistic state intervention should be avoided. As a result, it is up to physicians to enact professional regulations aimed at closing regulatory gaps, and the question then arises as to whether this task has been performed in a persuasive way so far.

Professional Regulation

Throughout Europe, medical associations have addressed the issue of sponsorship of medical education. The common starting point is that sponsorship of medical education is generally allowed provided that certain rules are observed. Professional regulations are not aimed at prohibiting the cooperation between industry and medical profession but instead at controlling this cooperation so that the quality and independence of the medical profession remain assured. Regulatory principles aimed at achieving these goals are more or less the same everywhere: commercial support shall be used in an appropriate way; structure and content of educational programs shall be objective, balanced and independent; as far as possible generic names shall be used; associated promotion shall be clearly distinguished from the educational program; financial relationships shall be transparent.[6]

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[5] Comprehensive information on the development and structure of continuing medical education in Europe is available at the website of the *Union Européenne des Médecins Spécialistes* (European Union of Medical Specialists; U.E.M.S.); www.uems.net.

[6] See e.g. the Assessment criteria for continuing education meetings of the *KNMG* (Royal Dutch Medical Association): "…2. Objectivity of the program: a) The participants are provided with objective information only. This means an objective and balanced interpretation of the educational material, especially diagnostic and therapeutic possibilities etc.… b) If possible, generic names are used instead of brand

Certainly all these principles are well-intended and nobody would doubt their necessity and legitimacy. Yet the basic flaw common to these principles relates to their vagueness and ambiguity. Criteria such as "appropriate", "objective" or "balanced" leave too much room for interpretation. They do not provide for legal certainty in the wide grey area of sponsored educational events whose marketing character although not obvious, nevertheless present risks of undue influence. This is not to say that there are no specific professional regulations at all; indeed, one can also find rather detailed and definite requirements. However, those requirements confine themselves to single aspects of medical education such as the arrangement of associated commercial exhibits and thus at best, establish some sort of piecemeal approach to the regulation of sponsorships.

In any case, the question remains as to whether professional regulation serves as the best starting point in addressing the problem of sponsored medical education. Certainly medical education is a genuine matter for the medical profession. Therefore it would seem obvious that it should be up to the medical profession to self-regulate specific circumstances relating to medical education. Moreover, there are several key benefits to be derived from professional self-regulation: the particular experience of the profession; the protection afforded to the profession against paternalistic state intervention; the higher level of acceptance of self-regulation on the part of the profession. On the other hand, self-regulation also has its disadvantages — in particular the problem that those who self-regulate are at the same time those primarily affected by this form of regulation. As a result of exercising their functions at such close range and proximity, it is difficult to achieve a well-balanced reconciliation of interests. However, it is exactly this reconciliation of interests which is at stake here: the means whereby medical education is financed does not only affect the interests of doctors; it also affects the interests of the general public which depends on the objectivity and independence of medical education in order to get the best possible treatment according to the state of the medical art. It is therefore both legitimate and necessary to evaluate professional self-regulation with regard to sponsored medical education and to call for more specific and unambiguous standards.

Industry Self-Regulation

Physicians' professional regulation is not the only form of self-regulation which addresses the issue of sponsored medical education. Industry self-regulation also

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names. . . .". For another example see the Criteria for Approval of CPD Events of the *Royal College of Physicians of Edinburgh* (Guidelines — Continuing Professional Development): "1. Any commercial sponsorship or interests of the programme planner, presenters, or facilitators must be declared on the application form. 2. Any support, sponsorship or funding by commercial health care organizations has not influenced the structure or content of the educational programme."

addresses this issue. However, what has just been said about professional self-regulation applies even more to industry self-regulation. One cannot and need not expect industry to be impartial when self-regulating the sponsorship of medical education. Pharmaceutical companies' natural (and legitimate) objective is the maximisation of profits and the sponsorship of medical education is an effective marketing tool in achieving this objective. It is difficult to imagine that industry would therefore adopt a distant and critical perspective as regards one of its central marketing tools. Yet this distant and critical perspective is essential to achieving a conclusive and balanced system of regulation.

Surely there are numerous examples of industry self-regulation on pharmaceutical marketing practices in general and on the sponsorship of medical education in particular. On the international level one may refer to the IFPMA[7] Code of Pharmaceutical Marketing Practices and the EFPIA[8] Code of Practice on the Promotion of Medicines. Both codes also contain provisions specifically addressing the sponsorship of medical education. However, some of these provisions are so self-explanatory that one might be surprised that there is any need for regulation at all.[9] As regards the rest, the self-regulatory framework is essentially affected by general criteria such as "reasonable", "appropriate", or "moderate"[10] and thus again is only of limited significance. In any case industry self-regulation cannot and should not replace other regulatory approaches.

Advertising Law

In the quest for a different (and truly European) approach to the issue of sponsored medical education, one might consider having a look at the European Directive on the Community code relating to medicinal products for human use.[11] Articles 86 et seqq. of this Directive regulate pharmaceutical advertising. According to Article 86, the sponsorship of medical education is also one form of advertising and thus has to comply with the requirements of the Directive. In particular, Article 95 is of significance and allows hospitality to be offered at

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7) *International Federation of Pharmaceutical Manufacturers & Associations*.

8) *European Federation of Pharmaceutical Industries and Associations*.

9) See e.g. article 7.2 IFPMA Code: "Member companies may sponsor healthcare professionals to attend events provided such sponsorship is in accordance with the following requirements: …• Any sponsorship provided to individual healthcare professionals must not be conditional upon an obligation to prescribe, recommend or promote any pharmaceutical product."

10) See e.g. article 7.4 et seqq. IFPMA Code ("reasonable fees"; "appropriate venue"; "moderate and reasonable as judged by local standards").

11) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended by Directive 2002/98/EC, Directive 2004/24/EC and Directive 2004/27/EC.

events for purely professional and scientific purposes provided that two requirements are fulfilled: "such hospitality shall always be strictly limited to the main scientific objective of the event; it must not be extended to persons other than health-care professionals." Once again those requirements admittedly are rather general and indefinite. Yet it is the very peculiar character of every directive to provide only a general harmonising framework which then has to be further substantiated by the Member States.

Up till now, Member States have been reluctant to do so. Instead, national laws confine themselves to more or less reiterating the general terms of the Directive[12] or do not even comply with the basic principles of the Directive.[13] However this does not have to be the case. Ironically it is the law of a non-member state, namely Swiss law, which proves that the European Directive on medicinal products can provide a good starting point for regulating the sponsorship of medical education. It was the declared intention of Swiss legislature to adopt European law and thus European rules on pharmaceutical advertising have been incorporated into Swiss law. While the text of the relevant provisions is again more or less a repetition of the Directive's regulations, it is the official interpretation of those regulations by Swiss authorities which is of interest. In 2006 Swissmedic, the central Swiss supervisory authority for therapeutic products, published a detailed comment on the interpretation of Article 33 HMG[14] with regard to the sponsorship of medical education.[15] The guidelines set up by Swissmedic are as follows: educational events which last longer than half a day may only be sponsored if participants also make an appropriate financial contribution; the same is true for shorter events which are accompanied by more than a simple meal. Participants' financial contributions have to amount to at least one third of the costs; depending on the place and duration of the educational event, the hospitality being offered, and the relationship between organizer and sponsor, the required contribution may also be significantly higher. Hospitality which is more than standard must be fully paid by the participants themselves. Altogether Swissmedic's guidelines constitute not only rather strict but also very clear and unambiguous limits to the sponsorship of medical education.

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12) See e.g. Regulation 21 of the Medicines (Advertising) Regulations 1994 (as amended by the Medicines (Advertising Amendments) Regulations 2005).

13) See e.g. the German interpretation of sec. 7 HWG (Heilmittelwerbegesetz — German Health Care Advertising Act) which implements Articles 86 et seqq. of Directive 2001/83/EC. Whereas Art. 86 et seqq. of the Directive cover all forms of sponsored educational events, sec. 7 HWG shall only cover those events which solicit specific pharmaceutical products.

14) Heilmittelgesetz (Medicines Act); Article 33 HMG contains the general prohibition to grant pecuniary advantages or benefits.

15) Swissmedic Journal 1/2006, pp. 20-45.

Prospects

One need not agree with every aspect of the Swiss approach. However, it seems to be a simple as well as promising way to direct medical education back to its original purpose — namely, the provision of scientific and educational information. Basically, Swissmedic's guidelines do not prohibit doctors from preferring medical education in a holiday-like environment to medical education in a school-like atmosphere. Yet if the former educational event is costlier than the latter one, this might discourage doctors from choosing educational events which do not focus on their educational value. Furthermore, Swiss law shows that it is by all means possible to create a clear and consistent legal framework for the sponsorship of medical education. And last but not the least, it also shows that the European Directive 2001/83/EC can serve as a good starting point in doing so. It therefore seems to be a worthwhile goal for European health law on the basis of this Directive to strive for a common regulatory framework for the sponsorship of medical education in order to ensure the independence of medical education.

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