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Sponsorship of Medical Textbooks by Drug or Device Companies

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Abstract

Background: To study whether medical textbooks are sponsored by drug or device companies, and if so, whether they have tried to influence their contents.

Methods: Cross-sectional study of the medical textbooks written in Danish for graduate clinical courses at the University of Copenhagen and anonymous web-based survey of editors. For sponsored books, we also contacted the authors.

Results: Eleven of 71 medical textbooks (15%) were sponsored. We contacted 11 editors, and for 8 books that had authors that were not editors, we also contacted one author. Ten editors and 5 authors replied. One editor was contacted 5 times by the various sponsors concerning the content of specific chapters and in another case the sponsor had the content of a chapter changed regarding its own drug. Two of the authors noted that they did not know that the book was sponsored.

Conclusions: Sponsorship of medical textbooks was not uncommon and may lead to lack of academic freedom. Medical students may be particularly vulnerable to commercial influences, as they have had little or no training in commercial biases and generally believe what they read in textbooks.

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Introduction

The contact with the pharmaceutical industry starts early in the medical career. A survey showed that more than half of third-year medical students had been exposed to industry influences such as free food, small non-educational gifts, journal reprints, books and grand rounds.¹ The students generally had a positive attitude towards these activities. To regulate this relationship, medical associations, industry and governmental authorities have made policies and guidelines², and campaigns have been initiated to draw attention to the problem.³⁻⁵

A survey of doctors showed that medical textbooks were their preferred information resource.⁶ Medical textbooks are opinion-based and recommendations can conflict with the current evidence.⁷ As textbooks do not give the readers the possibility of inspecting the data and drawing their own conclusions, biased recommendations based on conflicts of interest could lead to suboptimal clinical decision making.

Sponsorship of scientific books has been described in relation to the tobacco^{8,9} and alcohol¹⁰ industries. A court case concerning off-label promotion of the epilepsy drug gabapentin (Neurontin) revealed that Warner-Lambert paid over \$300,000 to support the production, printing and distribution of 75,000 copies of an epilepsy textbook.^{11,12} Half of the budget was allocated to soliciting interest among and delivering books to high prescribers of anticonvulsant agents. Apart from this case, sponsorship of medical textbooks has to our knowledge not been described previously and has not been investigated empirically. In this study, we describe sponsorship of Danish medical textbooks by the pharmaceutical and medical device industry and report a survey of the editors and authors.

Methods

Identification of sponsored textbooks

In December 2007, one author (AL) examined all medical textbooks written in Danish and potentially used for the graduate clinical courses in medicine at the Medical Faculty, University of Copenhagen available at either the University Medical Library or the University Medical Bookstore. We defined clinical courses as those which address treatment of patients (therefore, for

example, including pharmacology and microbiology, but excluding radiology and occupational medicine). Textbooks translated into Danish, or published before 1997, or written for other medical professions, or previous editions were excluded.

Data were extracted into a standardized datasheet on title, editors, authors, publisher, year of publication, edition, categorization according to clinical discipline, any statements of conflict of interest, and sponsorship. If a sponsorship was stated, information was extracted on sponsor's name and of sponsor's involvement.

We included all textbooks that were sponsored or that contained advertisements for drugs or medical devices.

Survey

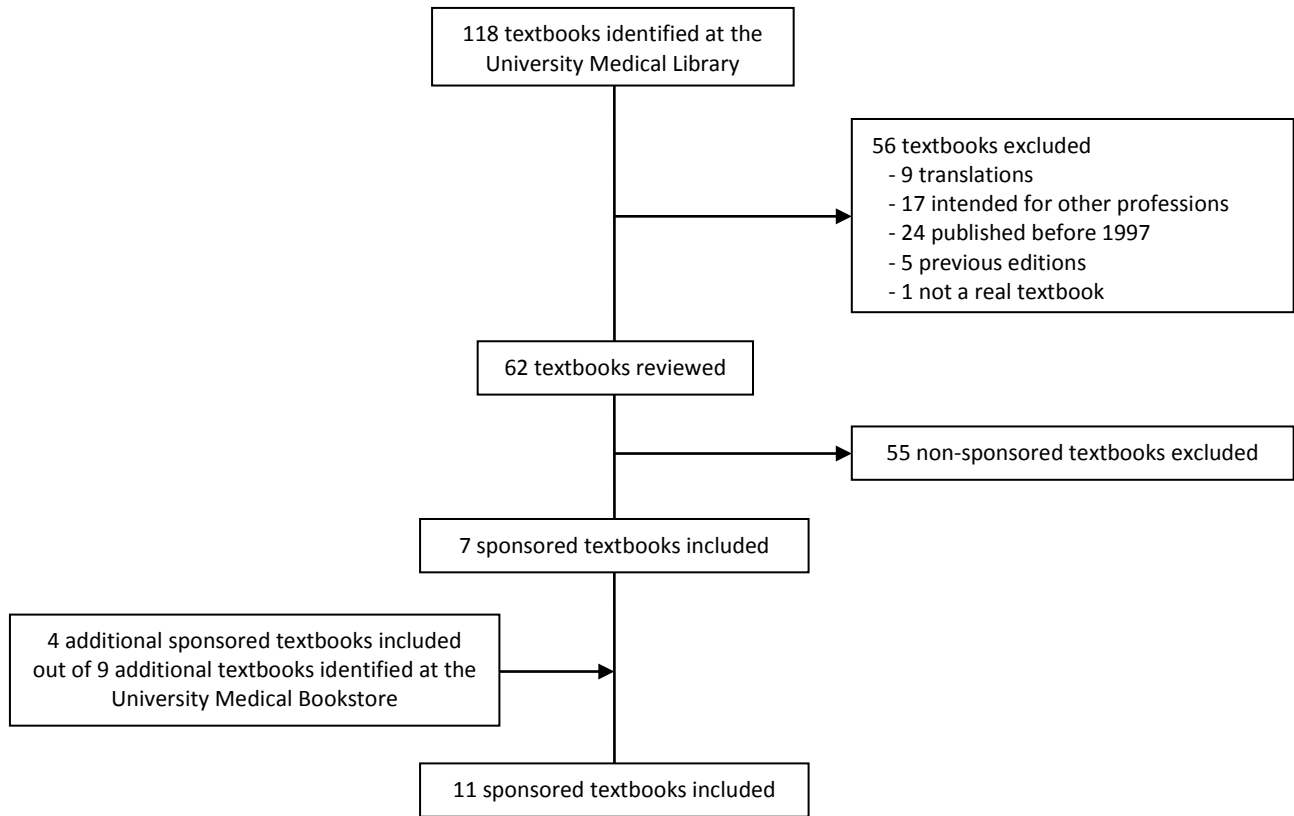
For each sponsored textbook, we contacted the first-mentioned editor and the first-mentioned author who was not also an editor. One author was a physiotherapist and as physiotherapists are not allowed to prescribe drugs, we chose the second author in this case. If a book had no description of editors (e.g. a book by a single author) or if it only described a technical editor (e.g. a non-physician without content knowledge) we regarded the authors as editors. We contacted these people in May 2008 via e-mail and asked them to fill in an anonymous web-based survey (SelectSurvey.NET 1.5.4) with 10 questions and a unique ID code in case we needed to contact them for clarifications. We sent a reminder by e-mail after one week and by letter after three weeks. We excluded duplicate replies, guided by the respondents IP address.

To investigate whether some textbooks without description of sponsorship were in fact sponsored, we did a second survey. In February 2009, we contacted the first-mentioned editors of the textbooks without sponsorship via e-mail and asked them to fill in an anonymous web-based survey (SelectSurvey.NET 1.5.4) regarding undisclosed sponsorship with 6 questions and a unique ID code in case we needed to contact them for clarifications. We sent a reminder by e-mail after 3 weeks.

Results

We identified 118 textbooks for clinical courses in Danish at the University Medical Library (Figure 1). Fifty-six were excluded: 9 were translations, 17 were

Figure 1. Flow chart of inclusion of textbooks



intended for other professionals than physicians (e.g., nurses, physiotherapists and psychologists), 24 were published before 1997, 5 were previous editions, and 1 was not a textbook, but a drug information guide. Of the 62 remaining textbooks, 7 were sponsored and included. We found an additional 9 books at the University Medical Bookstore of which 4 were sponsored, giving a total of 11 included sponsored medical textbooks (15% of 71 books).¹³⁻²³

Nine textbooks only included the name of the sponsors whereas one textbook also included whole-page drug advertisements from the sponsoring companies. This textbook is also available for free if the doctor agrees to receive a visit from a drug representative from one of the sponsoring companies. One textbook for general practitioners did not indicate sponsorship in the version we identified for our study, but the sponsorship was known to us because of earlier correspondence with the editor. Furthermore, we discovered that an alternative

version exists with a sponsorship statement and the company logo. Previously, this version could be obtained for free by contacting the sponsoring company, but it is now only available for free if the doctor agrees to receive a visit from the company's drug representative.

One textbook stated that the sponsors had no influence on the contents and recommendations, one that sponsorship included practical help and typing of manuscript, and four that the sponsorship covered printing cost and illustrations. The remaining 5 books had no such text. None of the books had any statements about editors' and authors' conflicts of interest.

We sent the e-mail invitation to 11 editors, 10 of whom were also authors, and to 8 authors who were not also editors. We received 15 unique surveys (79% response rate), of which 14 were complete. Ten respondents were editors and 5 were authors, one of whom had filled in the incomplete survey.

Initiation of sponsorship

Table 1 describes the responses to the first survey concerning sponsored textbooks. In 8 out of 10 cases, the editors participated in initiating the contact with the sponsoring companies. Four of them additionally explained that they sought help with production costs, in part to allow for higher quality of illustrations, as medical textbooks in Danish are expensive due to the limited number of potential purchasers. In two cases, it was the publisher who wanted the book to be sponsored, and the editor had no influence on this decision.

One out of 4 authors stated that he had had influence on whether the book should be sponsored, but not on who the sponsor should be. Two other authors stated that they did not know that the textbook they authored was sponsored before receiving our survey.

Agreements with sponsoring companies

Four out of the 10 editors and 1 out of 5 authors stated that they were presented with written information from the publisher that described the sponsor's influence, or lack thereof, on the editorial process and publication. Nine out of 10 editors stated there were no explicit terms in the agreement on sponsorship regarding

Table 1. Answers to survey about sponsorship of medical textbooks

Respondents		Editors	Authors*
No. of invitations sent		11	8
No. of responses received		10	5
Who took initiative to seek sponsorship? (more than one answer possible)	Editors	8	1
	Co-authors	0	0
	Publisher	5	0
	Companies	1	0
	Other	0	0
	Don't know	0	3
Had you as an author or editor any influence on the decision to seek sponsorship?	Yes	8	1
	No	2	3
If yes, did you have any influence on who the sponsor should be?	Yes	8	0
	No	0	1
Were you as author or editor presented with written information from the publisher that described sponsors influence, or lack of, on the editorial process and publication?	Yes	4	1
	No	6	4
Agreement on sponsorship:	No explicit terms	9	4
	Wanted to see chapter/book before agreement	1	0
	Other	0	0
Which influence did the sponsor have on the editorial process?	None	8	1
	Notify company with no explicit terms	0	0
	Notify company with right to comments	1	0
	Notify company with right to approval	0	0
	Other	1	0
	Don't know	0	3
Did you at any time have direct contact with the sponsor?	Yes	8	0
	No	2	4
Did you as author or editor receive fee from:	Sponsors	1	0
	Publisher	9	4
	Other	0	0

*One author did not respond to all questions in the survey

editorial independence, but in the last case some of the sponsoring firms wanted to see a draft of a chapter or the whole book before decision on sponsorship.

Contacts with sponsoring companies after the agreement

Two editors described that the sponsoring companies had contacted them after the agreement concerning the content of the textbook. In the first case, the editor had no influence on sponsorship, but was contacted by sponsoring companies approximately five times concerning questions in relation to the indication and choice of drug recommendations in specific chapters. The editor sent the questions to the authors of the specific chapters and stated that in no cases were the contents of the chapters changed.

In the second case, the editor - who was also the sole author - had no direct contact with the sponsoring company, but was contacted indirectly through the publisher. The publisher wanted the author to rewrite a chapter concerning recommendations on a drug produced by the sponsoring company. The publisher stated that the indications for the drug were not updated with the current evidence, as the indications were broader than what the author had written. The publisher then supplied the author with recommendations that the author was sure originated from the sponsoring company. When the author asked the publisher if these recommendations came from the sponsoring company, the publisher denied it. The author then refused to change the contents and the publisher rewrote the chapter and threatened the author with legal action if he intervened. Due to the specific details of this answer the anonymity was broken and it was later verified through contact to the editor that this was the book where the sponsorship was concealed.

Undisclosed sponsorship

We sent an e-mail invitation to the first-mentioned editor of the 60 textbooks without any description of sponsorship and received 43 unique surveys (72% response rate), which were all complete. Forty replied that the textbook was not sponsored while 3 replied that they did not know. One of the editors who replied that the textbook was not sponsored stated that a previous edition from 1985 received industry support for production costs.

Discussion

We identified eleven sponsored medical textbooks in Danish for graduate clinical courses. We found that in most cases the editors initiated the sponsorship agreement to improve the graphical quality of the textbooks and lower sales prices, and that in most cases the sponsoring firms did not have any influence on the editorial process and the contents of the books. However, in one case the sponsoring companies contacted the authors regarding questions to the contents of the book, and in another case where sponsorship was concealed, the sponsoring company indirectly changed the contents of a chapter through contact with the publisher without the author's approval.

Our study is limited by its small sample, by being restricted to Danish medical textbooks and by our choice of surveying only some of the editors and authors. It can be debated whether our findings of sponsorship are related to the fact that Danish is only spoken by a small number of people. One editor replied that more than 1000 copies sold per year is considered a huge success, and another remarked that his estimated income from producing the book amounted to 12 US cents per hour. Editors and authors can therefore be tempted to seek sponsorship in order to compete with cheaper books written in English. Even so, we have identified serious problems of general interest that we discuss below.

Unknown sponsorship

In three cases, the editors of textbooks without statements about sponsorship did not know whether the textbook was sponsored. In two other cases the authors of sponsored textbooks firstly became aware of this fact when they received our survey. This lack of transparency is a serious oversight, as potential editors and authors have been deprived of the possibility to decline the invitation, due to the sponsorship, in order to protect their reputation and scientific integrity. Furthermore, authors obviously cannot state their conflicts of interest in future publications when they don't know about them, and they might therefore undeservedly become suspected of misconduct, or of having broken the rules they are expected to live up to. For example, the authors of an article that was published in the online version of the BMJ²⁴ expressed concern subsequently²⁵ that they had not been

informed that their paper was sponsored by a drug company. Underneath the series name ("Medical Milestones"), and almost as if it were part of the title of their paper, this text appeared: "Publication of this online supplement is made possible by an educational grant from Astra Zeneca", and a drug ad was the banner along the top of the page. Two of the authors are Cochrane Centre Directors and questions had been raised with them about whether they had followed Cochrane policy regarding receiving support from industry. It is also problematic that concealed sponsorship makes it more difficult for authors to judge whether comments or requests for changes from the editors are sound or are commercially motivated. In one of our cases, the wish to change the contents of a chapter was only discovered as originating from the sponsor because of the author's knowledge about concealed sponsorship of the textbook.

A non-clinical textbook not included in our sample was "Rational Diagnosis and Treatment"²⁶ that is an obligatory textbook for the course on theory in medicine. A previous edition²⁷ was translated into Polish²⁸, but it was not made clear at the outset that it would be sponsored. This was revealed to the second author when much of the translation had already taken place and when it was difficult to back out. The second author was one of us, and he would not have accepted the sponsorship if it had been discussed openly from the outset. The book is sponsored by Pfizer and Glaxo-Smith Kline, and this industry sponsorship is particularly unfortunate for this book, as it was written to promote the principles of evidence-based medicine. In contrast, the aim of the drug industry is to sell as many drugs to as many people as possible, and flawed research and marketing often leads to irrational prescribing and overprescribing.²⁹

Editorial independence and authorship

In two cases the sponsor tried to influence the contents of the textbook. In one case, it was part of the agreement between the sponsors and the participating editor and authors that the sponsors were allowed to read the whole book or selected chapters and to comment on the contents before they decided whether they would sponsor the book. The authors were contacted approximately five times by the sponsoring companies with questions. While the editor stated that no changes were made, it is nevertheless problematic,

as self-censorship might have occurred. Editors and authors may be tempted to spin the contents to attract sponsors and to avoid withdrawal of sponsorship. The latter seemed to be the problem in the second case where the sponsoring company by contacting the publisher accomplished changes to the contents of a chapter with recommendations on a drug produced by the company. We suggest that, at the very least, agreements regarding editorial processes, authorship and sponsorship should be drawn up to support academic integrity, similar to authorship of scientific articles.³⁰ Furthermore, medical textbooks should describe what the sponsorship covered, what the conditions were, and whether the sponsor had any influence on the text.

Transparency of sponsorship

Only one textbook had any statements about the sponsors' influence on the editorial process, and five stated which production costs were covered by the sponsorship (e.g. secretarial assistance or graphical layout). None of the textbooks had any statements about the editors' and authors' ties to any of the sponsoring companies or companies that manufacture similar drugs or devices. This is problematic as medical textbooks may be more direct in their endorsement of specific treatments than research articles and seldom provide any data to back up recommendations. The readers must therefore rely on their trust in the editors and authors. Ties to industry can affect recommendations³¹ and conflicts of interests can therefore also be a problem in non-sponsored books. This suggests that textbooks should contain conflict of interest statements for editors and authors.

Conclusion

Sponsorship of medical textbooks was not uncommon and while few editors and authors described any problems in relation to the sponsors' possible influence on the contents, we discovered some major problems. We suggest that industry sponsorship of medical textbooks should be avoided, as it may lead to lack of academic freedom, for example through self-censorship. Medical students may be particularly vulnerable to commercial influences, as they have had little or no training in commercial biases and generally believe what they read in textbooks. If textbooks are sponsored they should at least live up to the same principles regarding

transparency and editorial independence as journal articles. Furthermore we recommend that all textbooks state any conflicts of interest for participating editors and authors.

Conflict of interest

We declare that we have no competing interests.

Contributors

AL conceived the study and wrote the draft protocol and draft manuscript. AL identified sponsored books, extracted data, developed the survey, contacted editors and authors and analysed the data. Both authors contributed to study design, acquisition and interpretation of data and writing the paper. Both authors are guarantor and gave final approval of the manuscript.

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Ethics

This study did not require ethical approval according to the Danish Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects.

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