Published in final edited form as:
Acad Med. 2009 September ; 84(9): 1226–1228. doi:10.1097/ACM.0b013e3181b18835.

Perspective: Disclosing Hidden Sources of Funding

David B. Resnik, JD, PhD [bioethicist]
National Institute of Environmental Health Sciences of the National Institutes of Health, Research Triangle Park, North Carolina.

Abstract

In this article, the author discusses ethical and policy issues related to the disclosure of hidden sources of funding in research. The author argues that authors have an ethical obligation to disclose hidden sources of funding and that journals should adopt policies to enforce this obligation. Journal policies should require disclosure of hidden sources of funding that authors know about and that have a direct relation to their research. To stimulate this discussion, the author describes a recent case: investigators who conducted a lung cancer screening study had received funding from a private foundation that was supported by a tobacco company, but they did not disclose this relationship to the journal. Investigators and journal editors must be prepared to deal with these issues in a manner that promotes honesty, transparency, fairness, and accountability in research. The development of well-defined, reasonable policies pertaining to hidden sources of funding can be a step in this direction.

Mainstream media and scholarly journals alike are rife with coverage of conflict-of-interest (COI) issues in biomedical research. Researchers and the journals in which they publish their work are held to strict policies about disclosing sources of funding and potential COIs. However, even these strict guidelines do not adequately address the question of hidden sources of funding. To address this widely unexplored but highly important issue, I discuss ethical and policy issues related to the disclosure of hidden sources of funding in research. I argue that authors have an ethical obligation to disclose hidden sources of funding and that journals should adopt policies to enforce this obligation. Journal policies should require disclosure of hidden sources of funding that authors know about and that have a direct relation to the authors' research. To stimulate this discussion, I describe a recent case reported in the media.

Introductory Case Study

On October 26, 2006, the *New England Journal of Medicine* published a study conducted by the International Early Lung Cancer Action Program (IELCAP) investigators, which examined the use of low-dose computed tomography (CT) scanning to detect clinical stage I lung cancer tumors. The study reported that lung cancer was detected in 494 out of 31,567 asymptomatic participants at risk for lung cancer, 85% of whom had stage I lung cancer. Eighty-eight percent of the participants with stage I lung cancer survived at least 10 years, and 92% survived 10 years if they underwent surgery within one month of diagnosis. The authors concluded that their results show that CT scanning can detect curable lung cancers.[1] If the results of this study are reproducible, this would be a very significant finding, because the diagnostic test currently in use, chest X-ray, is not very effective at detecting early-stage

Correspondence should be addressed to Dr. Resnik, 111 Alexander Drive, Box 12233, Research Triangle Park, NC 27709; telephone: (919) 541-5658; fax: (919) 541-3845; (resnikd@niehs.nih.gov).

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lung cancer. Because most tumors are not detected until they have reached an advanced stage, lung cancer is often fatal.[1]

The IELCAP study was disputed almost as soon as it was published. On March 7, 2007, another team of investigators published a study in the *Journal of the American Medical Association* raising doubts about the IELCAP research. These investigators found that CT scans increase the rate of lung cancer diagnosis and surgical treatment but do not reduce lung cancer mortality and can expose patients to unnecessary surgery.[2] In 2002, before the publication of the IELCAP study, the National Cancer Institute had initiated a clinical trial to examine the effectiveness of CT scanning in lowering lung cancer mortality. The trial should be completed in 2009.[3]

Eighteen months after the IELCAP study appeared in print, *The New York Times* and *The Cancer Letter* published stories investigating the sources of funding related to this research. The study investigators had disclosed in their article that that their research was funded, in part, by the Foundation for Lung Cancer: Early Detection, Prevention & Treatment (LCEDPT). *The New York Times* examined tax records from the LCEDPT and found that most of its funding came from a $3.6 million grant from the Liggett Group, a tobacco company that manufactures several different cigarette brands.[4] The newspaper also reported that Claudia Henschke, a professor of radiology at Weill Cornell Medical College, the lead author of the IELCAP study, is the president of the LCEDPT and that one of her collaborators, David Yankelevitz, also a professor of radiology at Weill Cornell Medical College, is its secretary-treasurer.[4] *The Cancer Letter* published a story revealing that Henschke and Yankelevitz had failed to disclose 27 patents on methods for assessing tumor growth and regression following imaging tests.[4,5] Critics accused the IELCAP investigators and the Liggett Group of trying to hide the source of funding for lung cancer research, a strategy other tobacco companies have used before.[4] Henschke and Yankelevitz denied this allegation.[4]

The CT screening for lung cancer study raises important issues concerning the disclosure of financial interests in research. Issues related to disclosure of hidden sources of funding remain largely unaddressed in scholarly discussions of COIs in research, and financial disclosure policies adopted by biomedical journals do not require authors to disclose these funding sources.[6] For example, the International Committee of Medical Journal Editors Uniform Requirements for Manuscripts Submitted to Biomedical Journals, a set of policies followed by over 670 biomedical journals, including the *New England Journal of Medicine*, does not mention any obligation to disclose a funding source's source of funding.[7] The *New England Journal of Medicine* does not have any policies pertaining to the disclosure of a funding source's sources of funding.[8] This specific type of disclosure is important because private companies frequently choose to support research via private foundations instead of funding studies directly, which allows investigators and companies to evade financial disclosure requirements.[9] A growing number of private companies have also created front groups to promote their interests, claiming, for example, that they are patient advocacy organizations.[10]

Disclosing Hidden Sources of Funding

In thinking about the disclosure of hidden sources of funding, we must distinguish between the ethical question (*Do authors have an ethical obligation to disclose hidden sources of funding?*) and the policy question (*Should journals adopt policies requiring authors to disclose hidden sources of funding?*). It will be useful to examine these questions separately, because different considerations apply to each.

Ethical questions

Concerning the first question, one could argue that the IELCAP investigators had an ethical obligation to disclose the LCEDPT's relationship to the Liggett Group. Various ethical principles, including honesty, openness, and transparency, imply that investigators have an obligation to disclose financial relationships that constitute a COI.[11] A COI is a situation in which an investigator has a financial, personal, or professional interest that has significant chance of interfering with his or her ability to fulfill his or her primary ethical or legal obligations in research.[11] An investigator with a COI may fail to honor his or her duties to conduct research honestly and objectively, which may bias his or her results and undermine the public's trust. Because COIs can bias research and undermine the public's trust, it is important to disclose these relationships to editors, reviewers, and other concerned parties.[12] Hidden sources of funding should be disclosed when they have a significant chance of biasing research or undermining the public's trust.

Policy questions

Although it is important to recognize that authors have an ethical obligation to disclose hidden sources of funding, this platitude may be empty if not accompanied by policies to enforce it. Four editors of the *New England Journal of Medicine* published an editorial in response to the IELCAP investigators' failure to disclose the Liggett Group's funding of the private foundation that supported their research. The editors asserted that "it is important that the ultimate source of funding be made clear to the *Journal's* readers . . . . It is the responsibility of authors to disclose fully and appropriately the sources of funding for their studies."[9] In that same issue of the journal, Henschke[13] published a letter clarifying the ultimate source of funding for the CT scanning study.

The editors' remarks seem reasonable, but they are too vague to constitute a workable policy. Any policy requiring authors to disclose hidden sources of funding must deal with some practical and ethical problems. First, authors may not be privy to information about hidden sources of funding. If authors do not know about hidden sources of funding, it seems unlikely that these sources significantly influence their research. If a funding source is not likely to affect research, it may not be reasonable for journals to make authors obtain information about it and disclose it. Looking for hidden sources of research funding could become a complex and onerous task for biomedical researchers and may not provide editors, readers, or the public with useful information. Second, an organization that funds research, such as a private foundation, is likely to have more than one funding source. Which of these sources should authors disclose? Should they disclose all hidden sources of funding or only those that could lead to bias or undermine the public's trust? Disclosing a hidden funding source that has no relationship to research may also not provide editors, readers, or the public with useful information.

One way to deal with these problems would be to place some definite limits on the requirement to disclose hidden sources of funding. Authors should be only required to disclose sources of funding they know about, which would relieve them of the obligation—and possibly the onerous burden—of searching for sources of funding. Disclosure could also be limited to sources of funding that have a direct relationship to articles submitted for publication. An article has a direct relationship to a source of funding if the subject matter of the article is closely related to the funding source's financial or other interests. Under this policy, the IELCAP investigators would have been required to disclose the LCEDPT's relationship to the Liggett Group, because the subject matter of their research—lung cancer screening—was closely related to the Liggett Group's financial interests and the investigators knew about this hidden source of funding. They would not have been required to disclose the relationship to the Liggett Group if they had no knowledge of this

relationship, or if the subject matter of their research had not been related to Liggett's financial interests.

Taking Proper Action

In conclusion, the episode concerning the Liggett Group's funding of CT scanning research through a private foundation is by no means an isolated incident. Because corporations now funnel a great deal of money through private foundations, it may become increasingly difficult for authors and journals to follow the money trail and make appropriate disclosures. Investigators and journal editors must be prepared to deal with these issues in a manner that promotes honesty, transparency, fairness, and accountability in research. The development of well-defined, reasonable policies pertaining to hidden sources of funding can be a step in this direction.

Acknowledgments

The author is grateful to Stavros Garantziotis and Ken De Ville for helpful comments.

This research was supported by the intramural program of the National Institute of Environmental Health Sciences, National Institutes of Health.

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